Monthly Steering Committee Meetings

January 26 2022 3-4PM ET

Pathology Innovation Collaborative Community

CLIA Waiver

- Create and review draft to be shared with CLIA state surveyors

Target audience… and why

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: QSO-20-21-CLIA

DATE: **March 26, 2020**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Clinical Laboratory Improvement Amendments (CLIA) Laboratory Guidance During COVID-19 Public Health Emergency

Memorandum Summary

- CMS is issuing this memorandum to laboratory surveyors to provide important guidance to surveyors and laboratories during the COVID-19 public health emergency, such as:
  - CMS' Exercise of enforcement discretion to ensure pathologists may review pathology slides remotely if certain defined conditions are met ,
  - Ensuring that laboratories located in the United States wishing to perform COVID-19 testing that apply for CLIA certification are able to begin testing as quickly as possible during the public health emergency,
  - Highlighting that laboratories within a hospital/University Hospital Campus may hold a

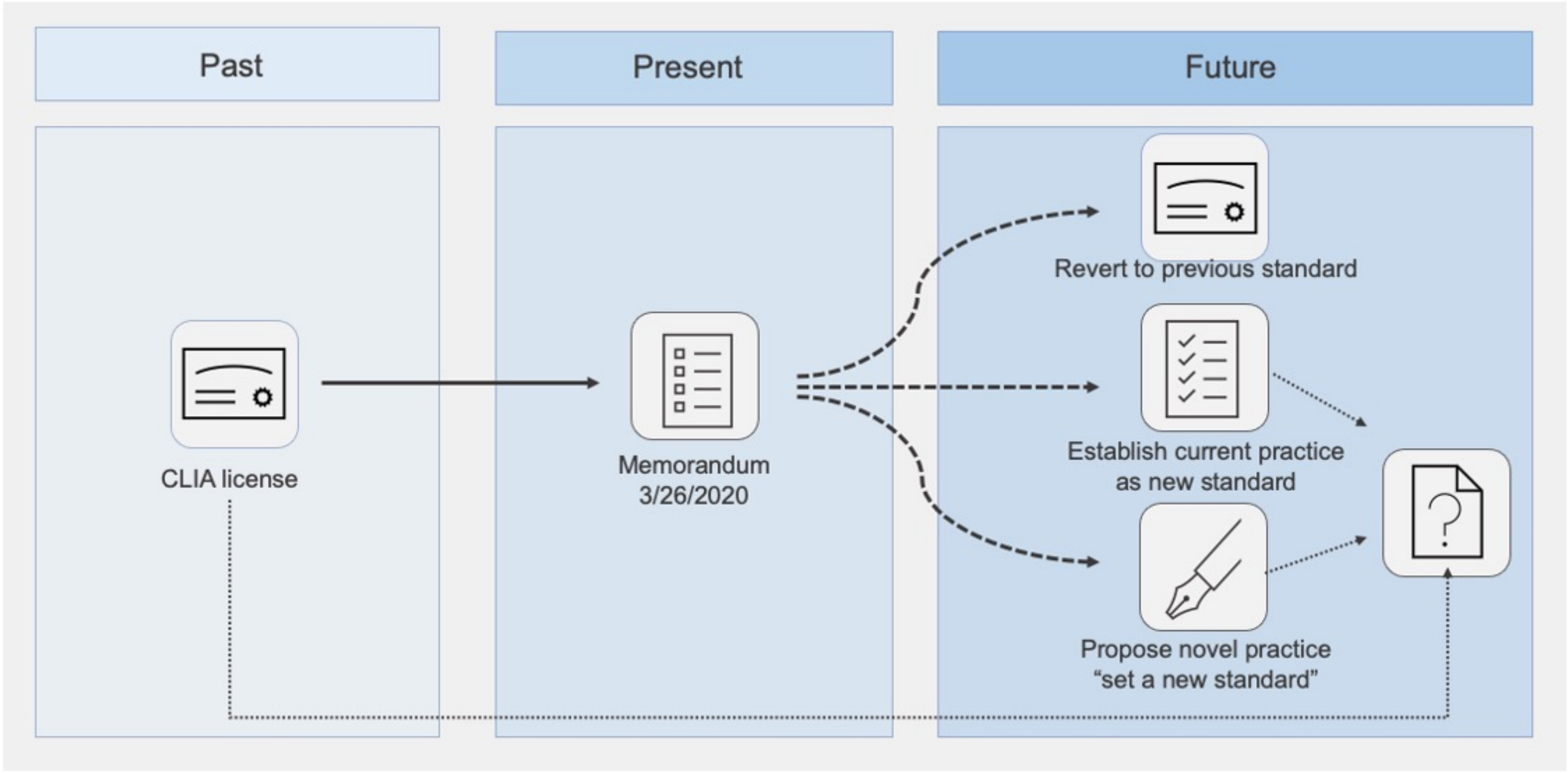
We want to clarify that laboratories performing LDTs as set forth in the FDA guidance are required to be CLIA-certified and meet the requirements to perform high complexity testing.

Contact: Questions about this document should be addressed to LabExcellence@cms.hhs.gov.

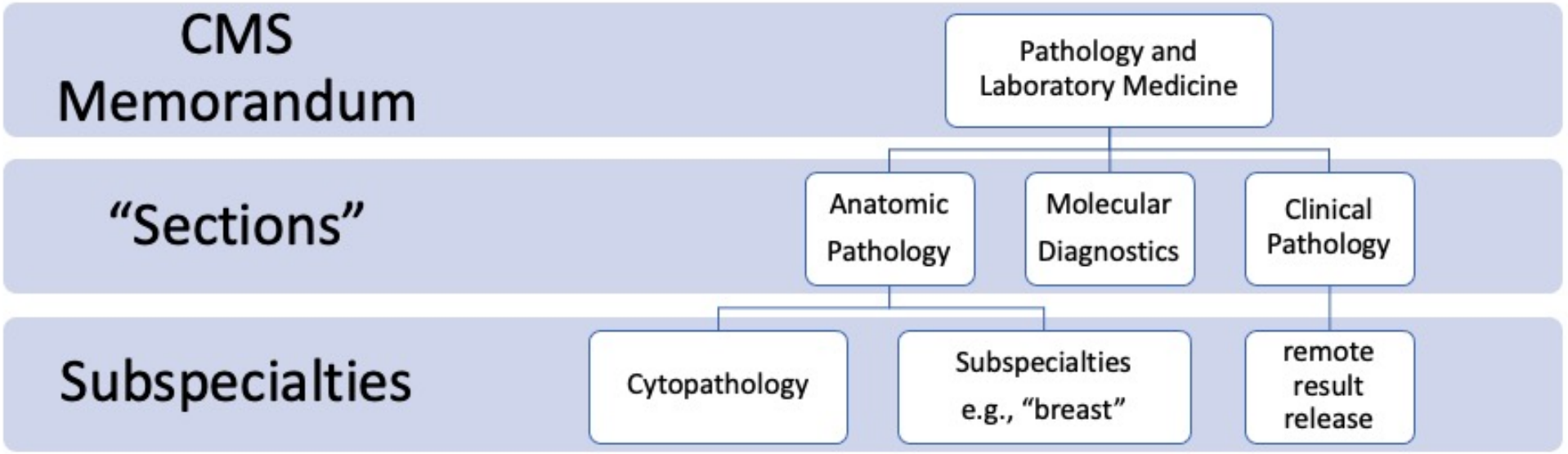
Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/
David R. Wright

cc: CLIA Branch Managers
CLIA Location Staff


Past
Present
Future
CLIA license
Memorandum
3/26/2020
Revert to previous standard
Establish current practice
as new standard
Propose novel practice
“set a new standard”

Scope



Function

signing out cases remotely	reviewing cases remotely	using digital pathology	using digital pathology remotely
• "key out results obtained at CLIA lab" **<VPN example>**	• "taking slides home, reviewing using a microscope in home office" **<home screening>**	• "using WSI in a CLIA laboratory" **<primary review>**	• "having a WSI process in CLIA laboratory. Primary review at an off-site location" **<primary remote review>**

Laboratories that choose to utilize temporary testing sites (e.g., for remote review and reporting of slides/images), may do so if the following criteria are met:

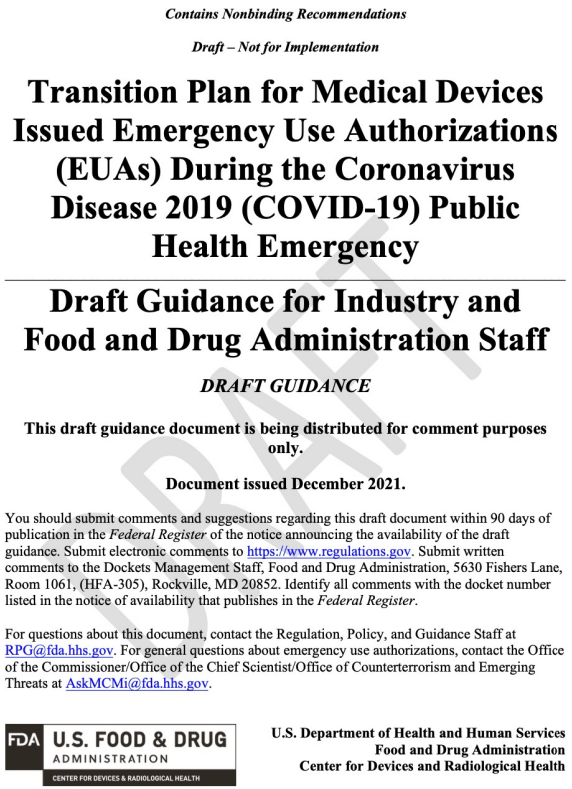
- 493.3(a) Basic rule. Except as specified in paragraph (b) of this section, a laboratory will be cited as out of compliance with section 353 of the Public Health Service Act unless it—
  (1) Has a current, unrevoked or unsuspended certificate of waiver, registration certificate, certificate of compliance, certificate for PPM procedures, or certificate of accreditation issued by HHS applicable to the category of examinations or procedures performed by the laboratory; or
- Per the regulations at 42 CFR §493.1105(a)(7) Slides. Cytology slide preparations must be retained for at least 5 years from the date of examination; Histopathology slides must be retained for at least 10 years from the date of examination; Pathology specimen blocks must be retained for at least 2 years from the date of examination; and Remnants of tissue for pathology examiniaiton must be preserved until a diagnosis is made on the specimen.
- Equipment, supplies, and reagents, and other similar items needed at the temporary site are not kept at a temporary testing site on a permanent basis.
- The temporary site complies with other applicable Federal law, including HIPAA.
- As per §493.1251 The primary site must have a written procedure manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.The Laboratory Director is not required to send but CMS may ask to inspect it in the future.

Proposal

- Additional regulatory input needed
- **Contact CLIA State Survey Agency Contacts**
  - Propose to review the "project"
  - Obtain their input
  - Consider a proposal

FDA Transition Plan

- Submit comments to draft guidance(s) by 3/23/22



Contains Nonbinding Recommendations

Draft – Not for Implementation

Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

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

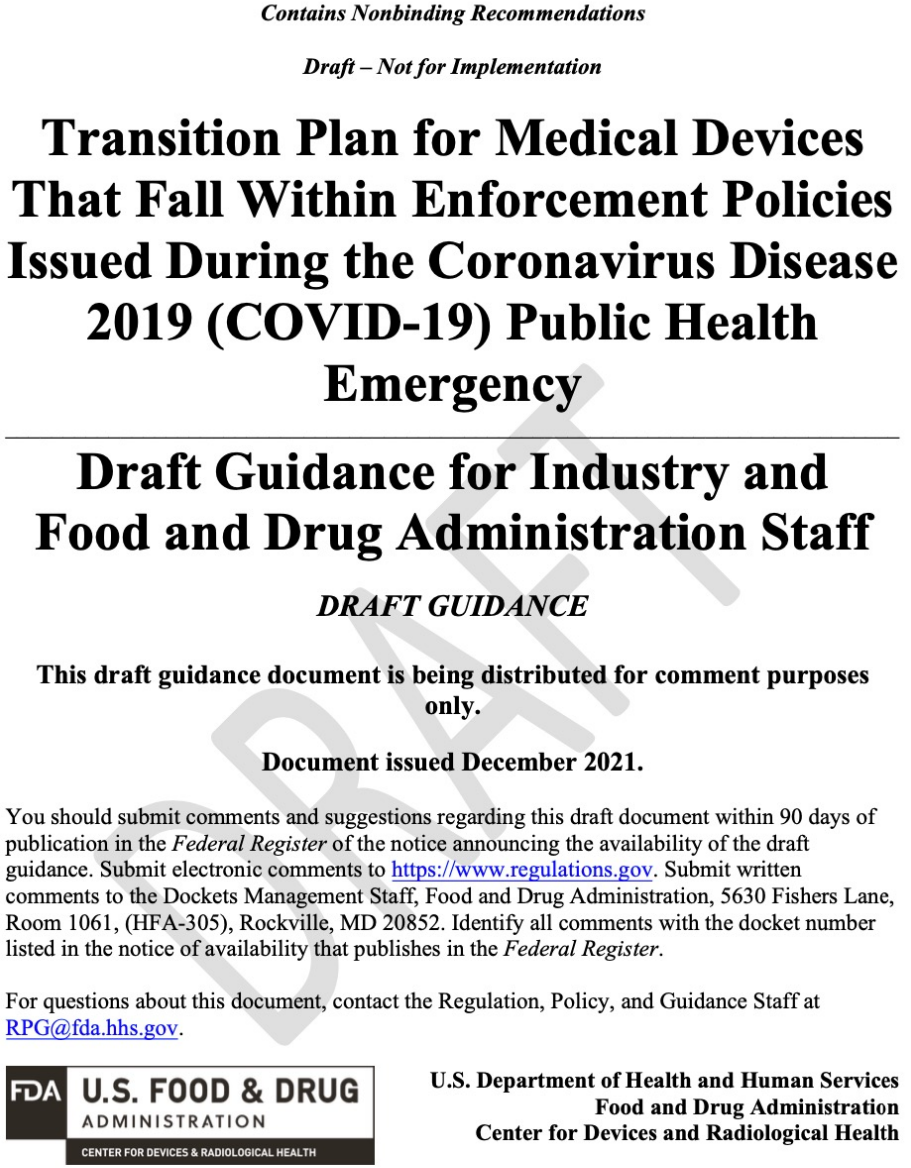
Document issued December 2021.

You should submit comments and suggestions regarding this draft document within 90 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, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document, contact the Regulation, Policy, and Guidance Staff at RPG@fda.hhs.gov. For general questions about emergency use authorizations, contact the Office of the Commissioner/Office of the Chief Scientist/Office of Counterterrorism and Emerging Threats at AskMCMi@fda.hhs.gov.

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

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health



Contains Nonbinding Recommendations

Draft – Not for Implementation

Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Draft Guidance for Industry and Food and Drug Administration Staff

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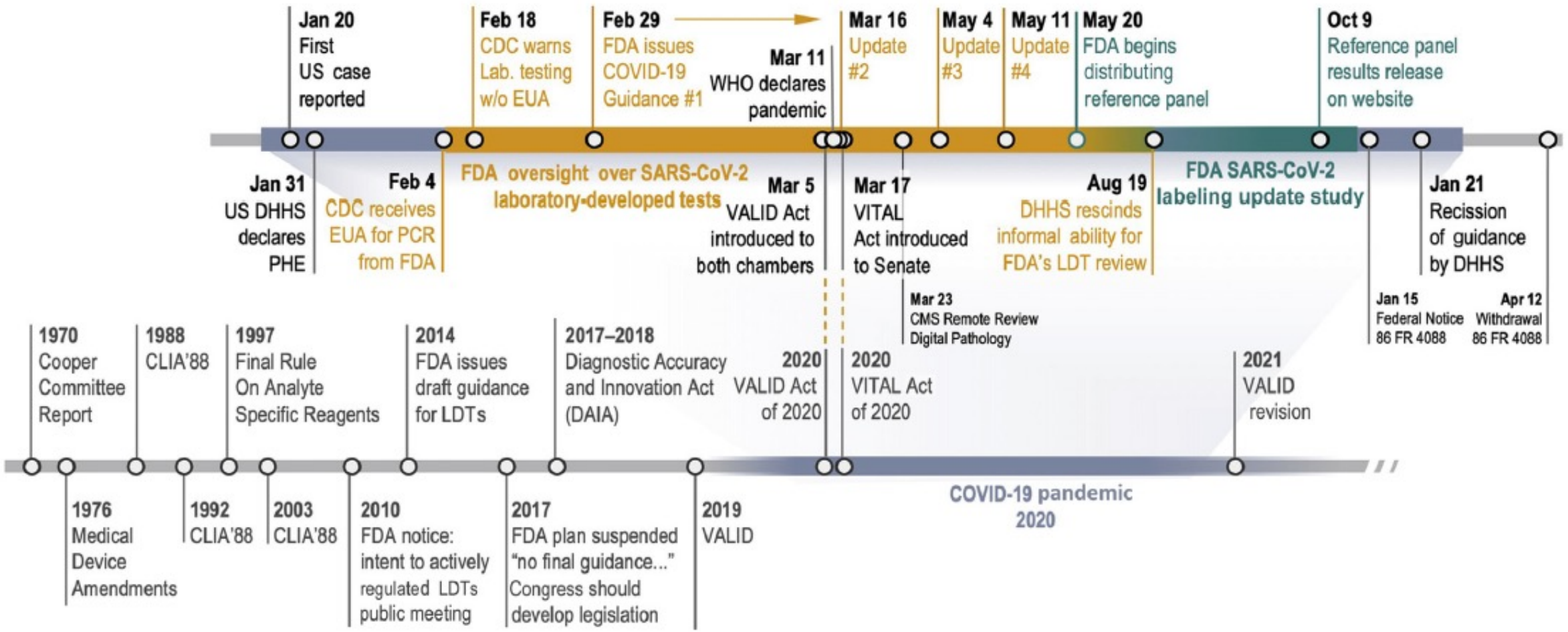
FDA U.S. FOOD & DRUG ADMINISTRATION CENTER FOR DEVICES & RADIOLOGICAL HEALTH

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Context



Marble et al., 2021 (J Mol Diagn.)

GUIDANCE DOCUMENT

Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Draft Guidance for Industry and Food and Drug Administration Staff

DECEMBER 2021

Download the Draft Guidance Document | Read the Federal Register Notice

Draft

Not for implementation. Contains non-binding recommendations.

This guidance is being distributed for comment purposes only.

ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

Center for Devices and Radiological Health

Featured papers

- **Bauer et al.** Making a science out of preanalytics: an analytical method to determine optimal tissue fixation in real-time
- **Morjaria et al.** Strategic thinking in test selection for mass SARS-CoV-2 testing
- **Lee et al.** Disruptive and sustaining innovation in telemedicine: a strategic roadmap
- **Bulten et al.** Artificial intelligence for diagnosis and Gleason grading of prostate cancer; the PANDA challenge

Bauer et al. Making a science out of preanalytics: an analytical method to determine optimal tissue fixation in real-time

PLOS ONE

RESEARCH ARTICLE

Making a science out of preanalytics: An analytical method to determine optimal tissue fixation in real-time

Daniel R. Bauer[1]*, Torsten Leibold[2], David R. Chafin[1]

1 Roche Tissue Diagnostics (Ventana Medical Systems, Inc.), Tucson, Arizona,
2 Raytheon Missiles & Defense, Tucson, Arizona, United States of America

* daniel.bauer.db2@roche.com

Abstract

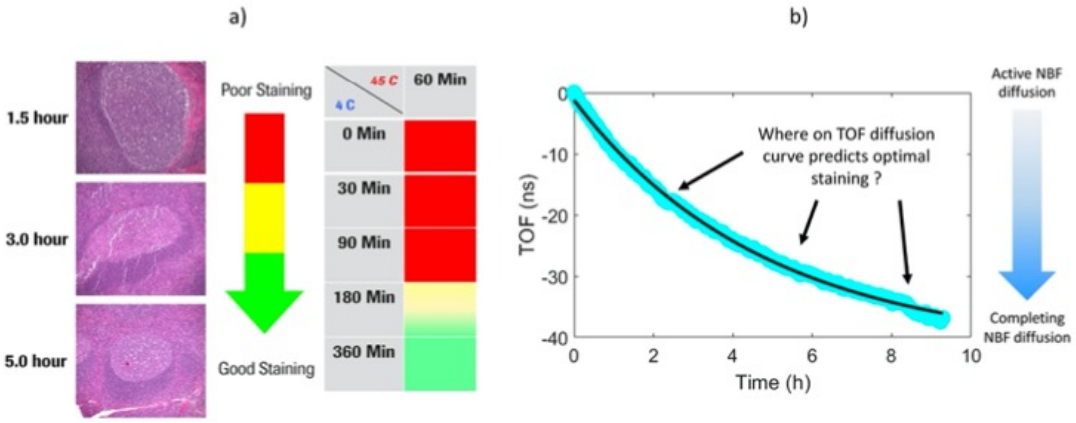


Fig 1. Correlating NBF diffusion times with stain quality. a) H&E images acquired with different cold soak times in NBF. Based on H&E based morphology, cold soak times of 1.5 hours, 3 hours, and 5 hours produced severely compromised, borderline, and exemplary staining, respectively. b) Example depiction of TOF diffusion curve with active NBF diffusion immediately after submerging tissue in NBF, manifesting with a rapidly changing TOF signal. Conversely, after several hours the tissue's rate of diffusion had significantly slowed as the tissue and NBF approached osmotic equilibrium.

https://doi.org/10.1371/journal.pone.0258495.g001

Morjaria et al. Strategic thinking in test selection for mass SARS-CoV-2 testing

OPINION

Strategic Thinking in Test Selection for Mass SARS-CoV-2 Testing

Sejal Morjaria,[a] Rosa Nouvini,[b] and S. Joseph Sirintrapun[c,*]

INTRODUCTION

help curb outbreaks. This is especially important for vulnerable communities that contain individu-

	Desired Features of Testing Strategy			Testing Regimen	Risk Assessment	Logistics and Policy
"Cold spot" Community						
Scenario 1: Asymptomatic individual screening and daily sporadic interactions between non-vulnerable individuals	Easy Accessibility	Fast TAT	NPV is a priority	POC testing (i.e. PATs)	Though not perfect, NPV is better and possibly acceptable, given the lower community prevalance. Likewise, the penalty of FN is lower, given the scenario is screening and non-vulnerable individuals. Consider that PPV is lower.	Restrictions and isolation for "spreader" individuals testing positive, particularly those interacting with vulnerable subpopulations. Follow-up of positive tests with confirmatory PCR.
Scenario 2: Individuals with continual interactions with vulnerable subpopulations	Easy Accessibility	Fast TAT	PPV and NPV is a priority	PCR	The high penalty for FP and FN results are best addressed by performing PCR testing regimens.	Increase PCR testing supplies and improve logistics for deployment to enhance accessibility and TAT.
"Cold spot" Community with limited testing capacity						
Scenario 3: Individuals developing a new onset of predictive COVID-19 associated symptoms	Easy Accessibility	Fast TAT	PPV and NPV is a priority	Start with POC testing (i.e. PATs). Develop serial POC testing regimens to strengthen trust in the POC results. Consider judicious use of follow-up PCR testing (when available).	NPV more trustworthy, particularly when a developed serial POC testing regimen is negative. PPV is lower, though developing a serial POC testing regimen may enhance the sensitivity.	Weighing the penalty of a FN, consider confirmatory PCR (if available) where the penalty is high. Or without PCR, blanket restrictions for all with symptoms where penalty is high.
"Hot spot" high RO, high COVID-19 prevalence community with limited testing capacity						
Scenario 4: Individuals developing a new onset cough	Easy Accessibility	Fast TAT	PPV and NPV is a priority	Start with POC testing (i.e. PATs). Develop serial POC testing regimens to strengthen trust in the POC results. Consider judicious use of follow-up PCR testing (when available).	PPV more trustworthy, negatives are more suspect.	Weighing the penalty of a FN, consider confirmatory PCR (if available) where the penalty is high. Or without PCR, blanket restrictions for all with symptoms where penalty is high. The latter may not be practical given that such communities in reality, regularly interact with vulnerable subpopulations. Therefore, efforts should be made to increase access to more accurate confirmatory tests like PCR.

What the testing regimen delivers for desirable features of the testing strategy.

What is not associated with the testing regimen and must be worked upon to meet the desirable features of the testing strategy.

NPV = Negative predictive value
PPV = Positive predictive value
POC = Point of care
FN = False negative
FP = False positive
PATs = Paper-based antigen tests
TAT = Turn-around time
RO = Level of contagiousness

Fig. 1. SARS-COV-2 testing strategy for 4 commonly encountered community scenarios.

Lee et al. Disruptive and sustaining innovation in telemedicine: a strategic roadmap

NEJM Catalyst

COMMENTARY

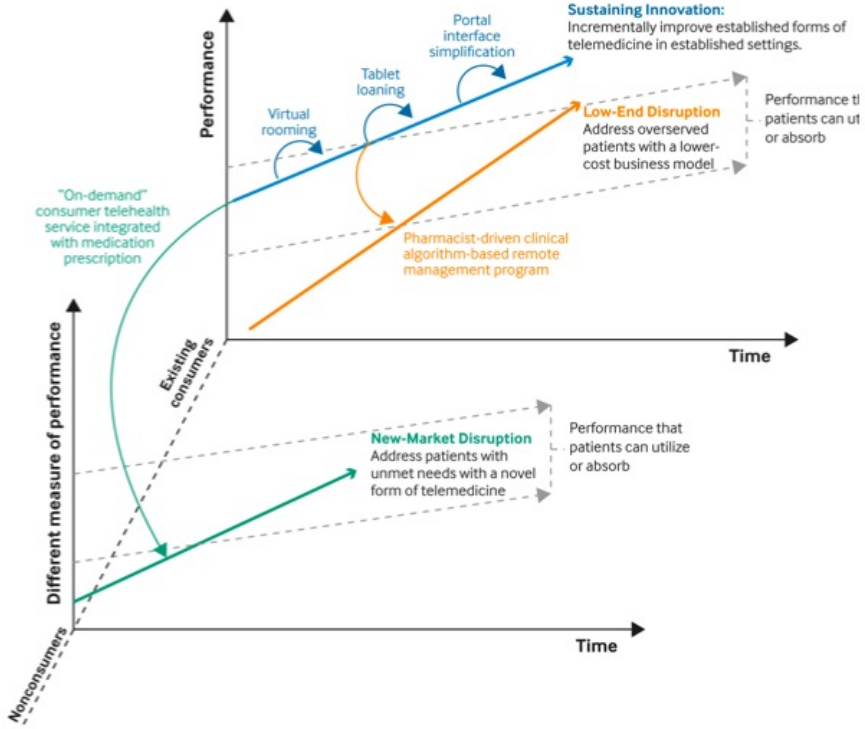
Disruptive and Sustaining Innovation in Telemedicine: A Strategic Roadmap

Simin Gharib Lee, MD, MBA, Alexander Blood, MD, William Gordon, MD, Benjamin Scirica, MD, MPH

DOI: 10.1056/CAT.21.0311

The Disruptive Innovation Model Applied to Telemedicine

In this framework, patients' performance demands (gray dotted lines) increase at a certain rate ove time and contrast with telemedicine performance, which either improves along a sustaining innovation trajectory, incrementally enhancing offerings to serve patients with the most complex needs (blue line), or along disruptive innovation trajectories, serving patients with more basic (orar line) or altogether unmet needs (green line). Examples specific to telemedicine of sustaining improvements to mainstream models as well as disruptive departures from these models are deta



Telemedicine as a Sustaining Innovation

Bulten et al. Artificial intelligence for diagnosis and Gleason grading of prostate cancer; the PANDA challenge

nature medicine

ARTICLES

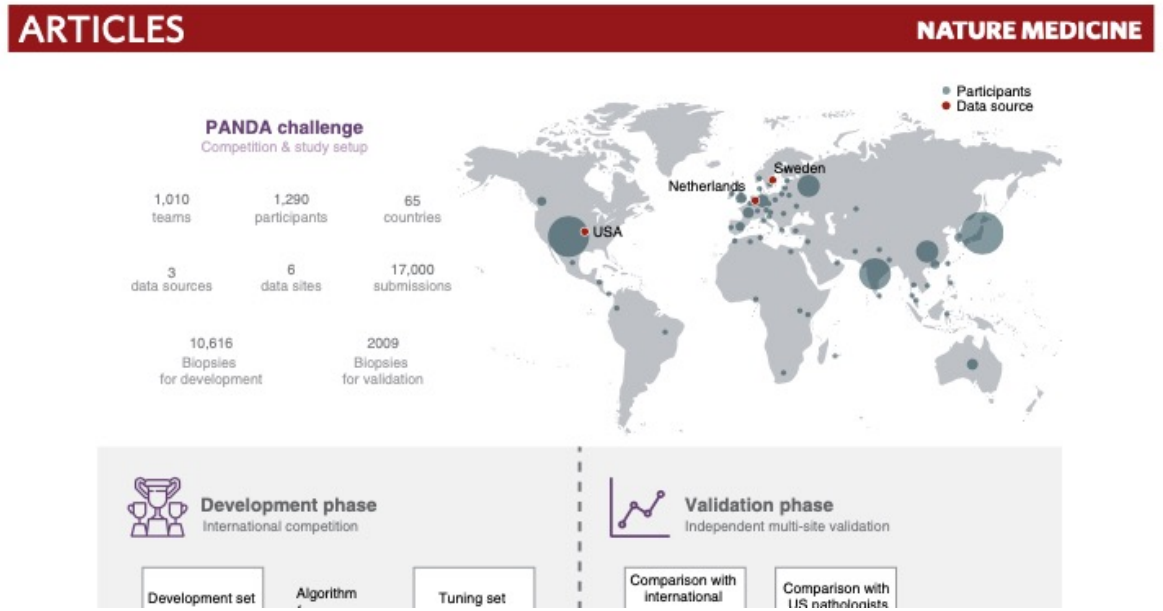
https://doi.org/10.1038/s41591-021-01620-2

Check for updates

OPEN

Artificial intelligence for diagnosis and Gleason grading of prostate cancer: the PANDA challenge

Wouter Bulten[1,60] ✉, Kimmo Kartasalo[2,3,60] ✉, Po-Hsuan Cameron Chen[4,60] ✉, Peter Ström[2], Hans Pinckaers[1], Kunal Nagpal[4], Yuannan Cai[4], David F. Steiner[4], Hester van Boven[5], Robert Vink[6], Christina Hulsbergen-van de Kaa[6], Jeroen van der Laak[1,7], Mahul B. Amin[8], Andrew J. Evans[9], Theodorus van der Kwast[10], Robert Allan[11], Peter A. Humphrey[12], Henrik Grönberg[2,13], Hemamali Samaratunga[14], Brett Delahunt[15], Toyonori Tsuzuki[16], Tomi Häkkinen[3], Lars Egevad[17], Maggie Demkin[18], Sohier Dane[18], Fraser Tan[4], Masi Valkonen[19], Greg S. Corrado[4], Lily Peng[4], Craig H. Mermel[4], Pekka Ruusuvuori[3,19,61], Geert Litjens[1,61], Martin Eklund[2,61] and the PANDA challenge consortium*



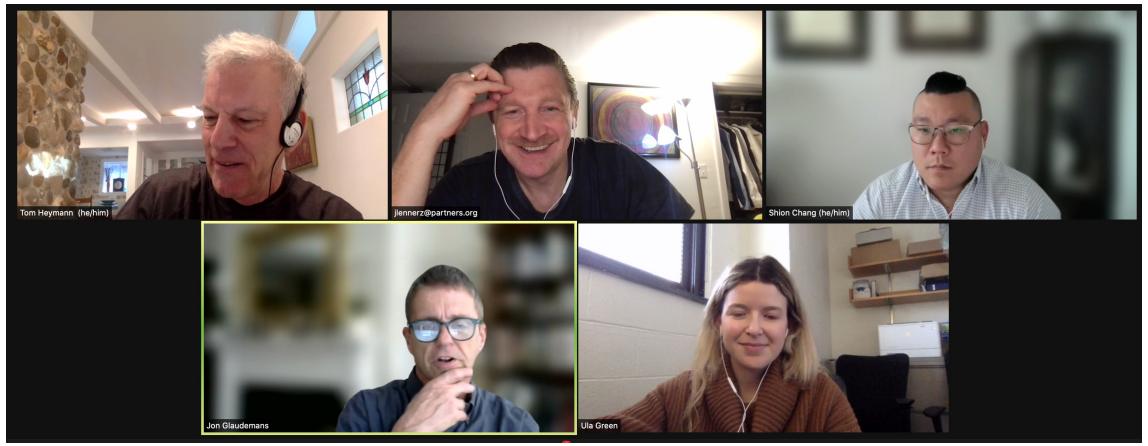
"On United States and European external validation sets, the algorithms achieved agreements of 0.862 (quadratically weighted κ, 95% confidence interval (CI), 0.840–0.884) and 0.868 (95% CI, 0.835–0.900) with expert uropathologists".

Patient Advocacy Update

- One of our key deliverables in 2022 is to engage more patient advocacy groups

Sepsis Alliance

- Initial introduction meeting by M. Tarver FDA
- First meeting on 1/19
- Patient advocacy
- Aims to become a collaborative community



APPIA

Phone: 919.314.6561

APPIA
Anatomical Pathology Patient Interest Association

THE APPIA MISSION

Cooperative industry partners dedicated to advancing anatomic pathology to benefit patient care by advocating and fostering quality, education, and best practices.

Home | About APPIA | Membership | Education | News & Initiatives | Contact

Anatomical Pathology Patient Interest Association

What is APPIA?

APPIA is the leading anatomic pathology

Membership

APPIA membership provides access to a

News & Initiatives

The Anatomical Pathology Patient Interest

APPIA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practices.
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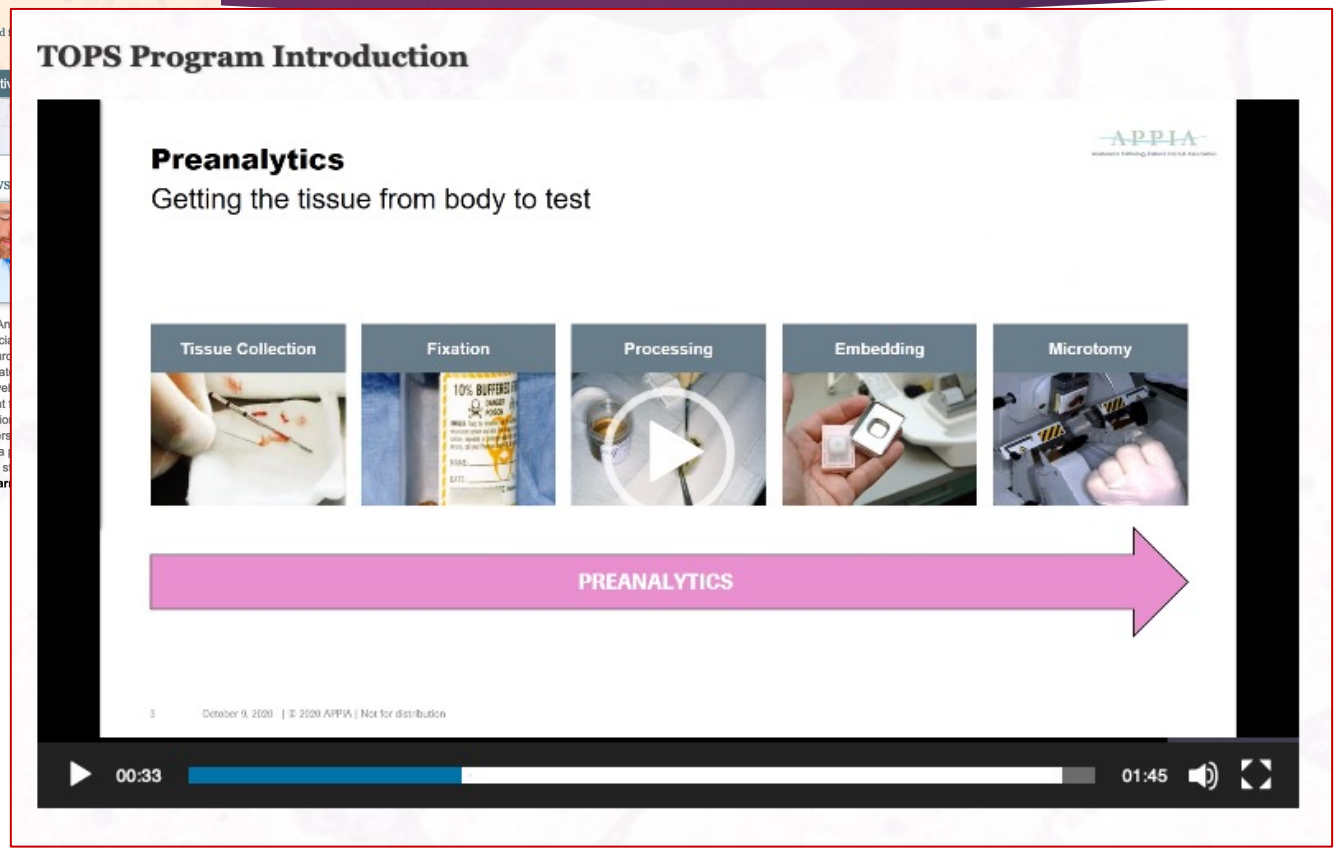
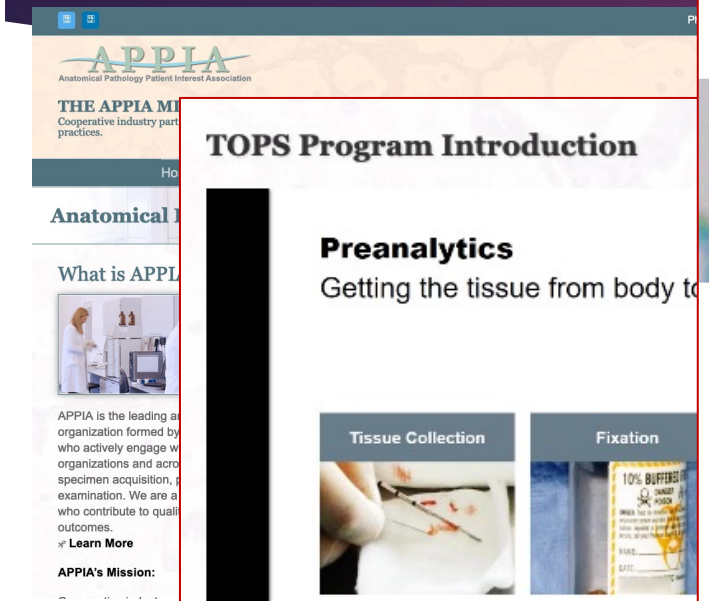
Anatomical Pathology Patient Interest Association
What is APPIA?
Membership
APPIA is the leading anatomic pathology organization formed by industry partners who actively engage with individuals and organizations and across all phases of specimen acquisition, preparation and examination. We are a resource to those who contribute to quality patient outcomes.
Learn More
APPIA's Mission:
APPIA membership provides access to a dedicated community, which together works to influence anatomical pathology with the primary aim to provide high-quality patient care in pathology. The organization's membership is represented by leading organizations and individuals across the globe. Plan to join this dynamic community of pathologists, scientists, technologists and industry representatives dedicated to advancing the industry.
Learn More


TOPS Program Introduction
Preanalytics
Getting the tissue from body to test
APPIA
Tissue Collection
Fixation
Processing
Embedding
Microtomy
PREANALYTICS
00:33
01:45

APPIA


APPIA
Anatomical Pathology Patient Interest Association
THE APPIA MI
Cooperative industry part
practices.
Anatomical
What is APPL
APPIA is the leading a
organization formed by
who actively engage w
organizations and acro
specimen acquisition,
examination. We are a
who contribute to quali
outcomes.
Learn More
APPIA's Mission:

TOPS Program Introduction
Preanalytics
Getting the tissue from body t
Tissue Collection
Fixation
October 9, 2020 | © 2020 APPIA | Not for distribution
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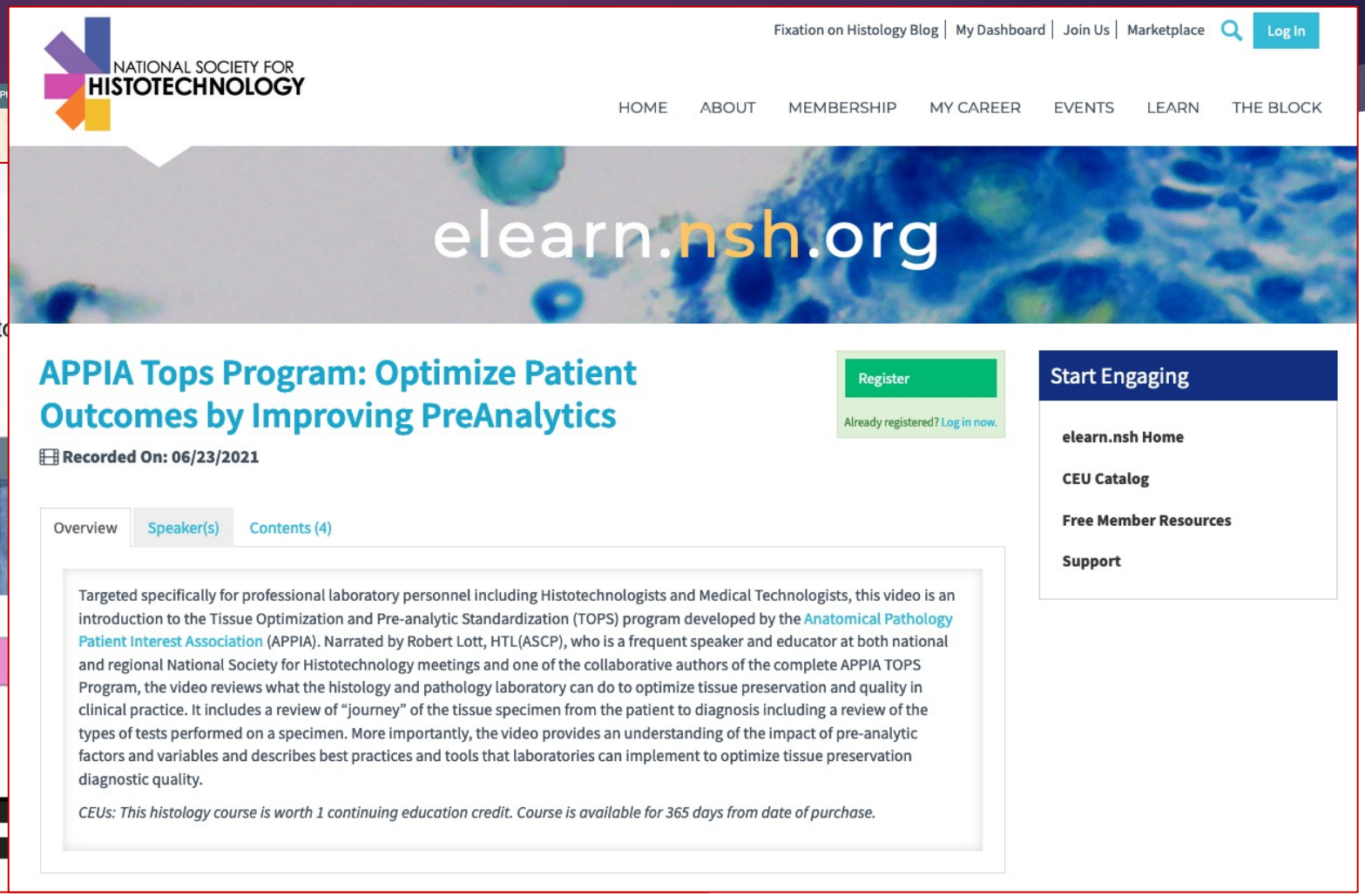

NATIONAL SOCIETY FOR HISTOTECHNOLOGY
Fixation on Histology Blog | My Dashboard | Join Us | Marketplace
Log In
HOME ABOUT MEMBERSHIP MY CAREER EVENTS LEARN THE BLOCK
elearn.nsh.org
APPIA Tops Program: Optimize Patient Outcomes by Improving PreAnalytics
Recorded On: 06/23/2021
Register
Already registered? Log in now.
Start Engaging
elearn.nsh Home
CEU Catalog
Free Member Resources
Support
Overview
Speaker(s)
Contents (4)
Targeted specifically for professional laboratory personnel including Histotechnologists and Medical Technologists, this video is an introduction to the Tissue Optimization and Pre-analytic Standardization (TOPS) program developed by the Anatomical Pathology Patient Interest Association (APPIA). Narrated by Robert Lott, HTL(ASCP), who is a frequent speaker and educator at both national and regional National Society for Histotechnology meetings and one of the collaborative authors of the complete APPIA TOPS Program, the video reviews what the histology and pathology laboratory can do to optimize tissue preservation and quality in clinical practice. It includes a review of "journey" of the tissue specimen from the patient to diagnosis including a review of the types of tests performed on a specimen. More importantly, the video provides an understanding of the impact of pre-analytic factors and variables and describes best practices and tools that laboratories can implement to optimize tissue preservation diagnostic quality.
CEUs: This histology course is worth 1 continuing education credit. Course is available for 365 days from date of purchase.

ISPOR

Title:
ADVANCING EXCHANGE OF DIGITAL HEALTH INFORMATION BY EMBRACING A NATIONAL TOKENIZATION MODEL FOR UNIQUE PATIENT IDENTIFICATION

Moderator:
Joe Lennerz MD PhD, Massachusetts General Hospital/Harvard Medical School, Boston, MA, USA)

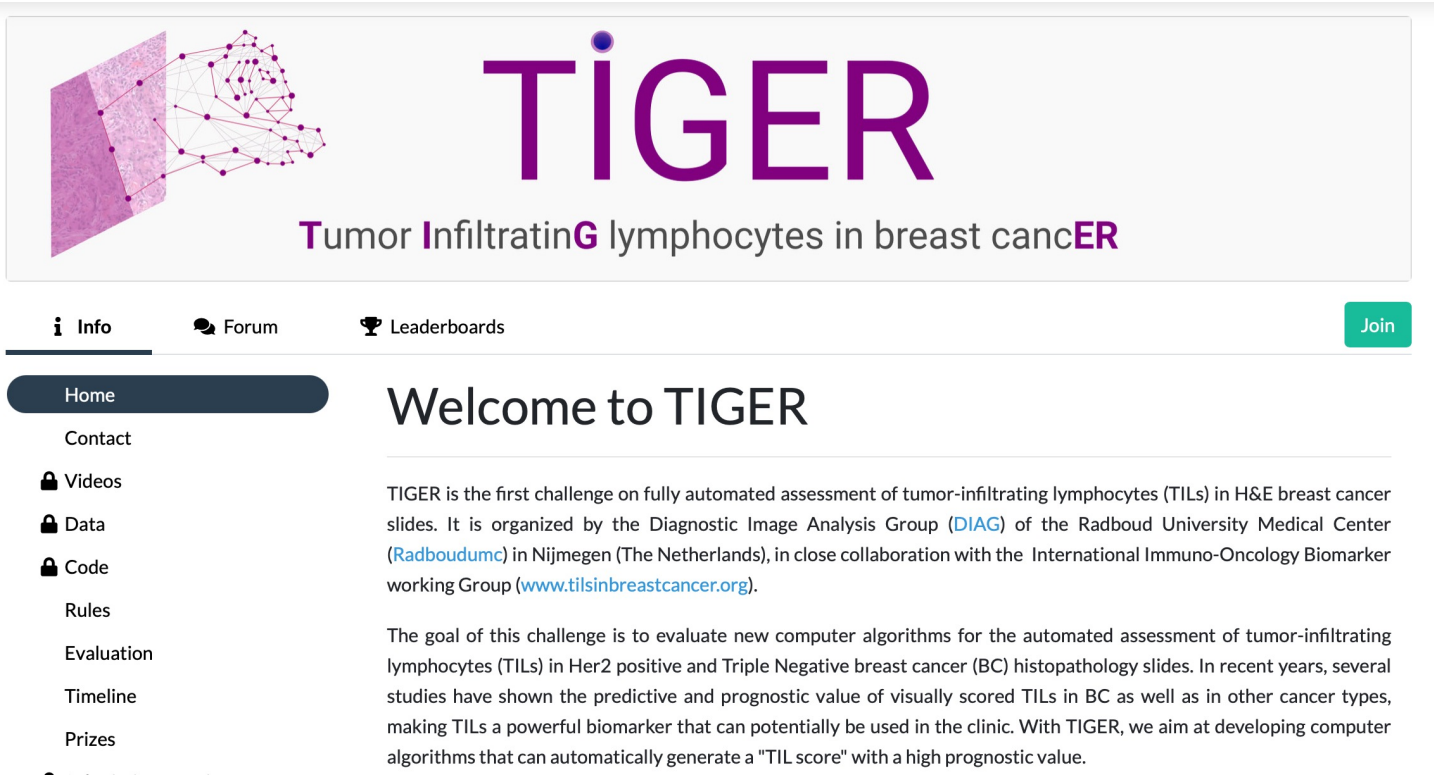
Panelists (must have 2-3 panelists from different organizations; please include name, degree(s), institution, city, state, country)

- S. Joseph Sirintrapun, M.D., Memorial Sloan Kettering Cancer Center, New York City, New York, USA
- Victor Brodsky, M.D., Washington University, St. Louis, Missouri, USA
- Bob Titus, CTO, Netcracker Technology Corp., Toronto, Ontario, Canada
- Jeff Allen, Ph.D., CEO, Friends of Cancer Research, Washington, D.C., USA

- Waiting on notification for submission of abstract
- We provide an overview of some of the questions around this topic

TIGER Grand Challenge

- TILS Grand Challenges



ONC (Office National Coordinator for Health Information Technology)

The Office of the National Coordinator for Health Information Technology

Project US@

Revision History

Date	Version	Description
6/16/2021		DRAFT initial release
1/7/2022	1.0	FINAL release

TECHNICAL SPECIFICATION FOR PATIENT ADDRESSES DOMESTIC AND MILITARY

FINAL VERSION 1.0

Current Version Date: 1/7/2022
Project US@ Technical Workgroup

HIT (ONC) Technical specifications

- Example of complexity of standardization

Incorrect Form	Correct Form
BIG BUSINESS INCORPORATED 12 EAST BUSINESS LANE, SUITE-209 KRYTON,TN 38188-0002	BIG BUSINESS INC 12 E BUSINESS LN STE 209 KRYTON, TN 38188-0022
PIZZA DELIVERY COMPANY 61-20 EAST RIVER DRIVE NEW YORK, NY 10021-0905	PIZZA DELIVERY COMPANY 61-20 E RIVER DR NEW YORK NY 10021-0905

FDA

U.S. FOOD & DRUG ADMINISTRATION

FDA Clinical Investigator Training Course

Real-World Evidence

8 December 2021

John Concato, MD, MS, MPH
Associate Director for Real-World Evidence Analytics
Office of Medical Policy
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

2022 Summer OSEL Regulatory Research Experience (SORRE) Announcement

The Office of Science and Engineering Laboratories (OSEL) at the FDA Center for Device and Radiological Health (CDRH) accelerates patient access to innovative, safe and effective medical devices through best-in-the-world regulatory science. We are composed of scientists and engineers who have a broad diversity of expertise from microbiology, chemistry, physics, data science to artificial intelligence and machine learning.

The SORRE Program is hosted by the OSEL Diversity, Equity, Inclusion, & Belonging Council (DEI&B) to increase underrepresented students to perform regulatory science research at the U.S. Food and Drug Administration (FDA).

The program has several paid and unpaid opportunities for students to engage in OSEL's Regulatory Science Research Programs, which consist of a variety of research projects primarily focused on laboratory research of medical devices.

The OSEL Regulatory Science Project Catalog below describes opportunities available for the 2022 Summer program. Please read each project description as you will need to select your top three.

Open Date: January 18th, 2022
Close Date: February 18th, 2022

PIcc Updates

- Progress by Truthing & Validation group
- Finalizing survey for TILS RS Project
- Updating website domain:
  Digitalpathologalliance.org → **pathologyinnovationcc.org**

MDIC

MDIC MEDICAL DEVICE INNOVATION CONSORTIUM + TMG COMPANIES

Emerging HealthTech

The MDIC Series | Clinical Diagnostics

MDICx: AI/ML Framework Public Comment Q&A

Tuesday, February 1, 2022 | 12:00PM – 1:00PM ET

Upcoming Events

Supporting Development of Diagnostic Tests for Unmet Needs

Friends of Cancer Research Virtual Meeting

Supporting Development of Diagnostic Tests for Unmet Needs

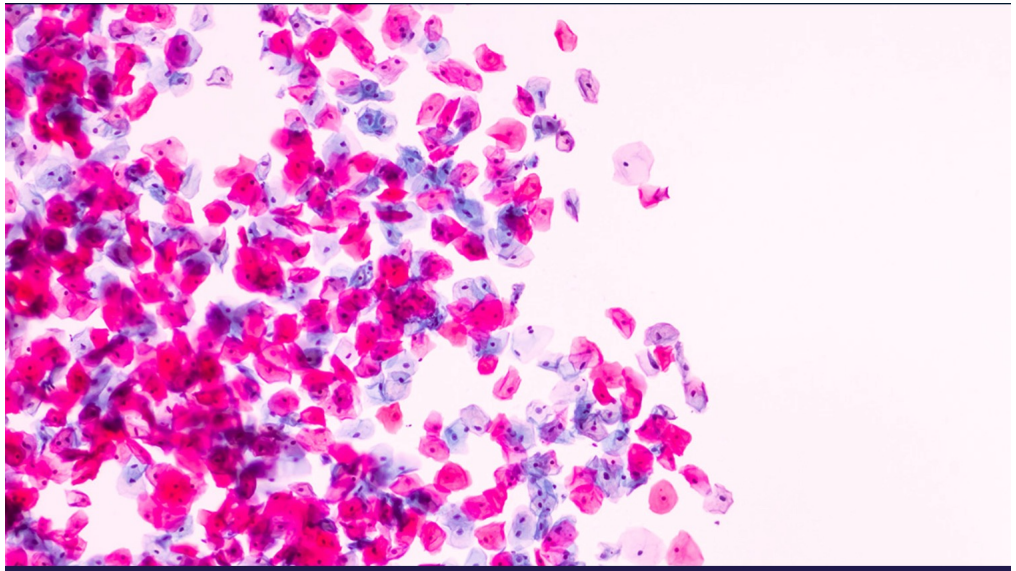
Tuesday, February 22, 2022

12:00PM EST - 1:00PM EST

Friends of Cancer Research (*Friends*) is proud to announce a new virtual meeting, **Supporting Development of Diagnostic Tests for Unmet Needs**.

During the past several months, experts from across health sectors have convened to design new approaches for drug/diagnostic co-development in the field of oncology and rare diseases. This forum will feature a new report describing recommended strategies and policy considerations to optimize diagnostic test development for rare populations into the future.

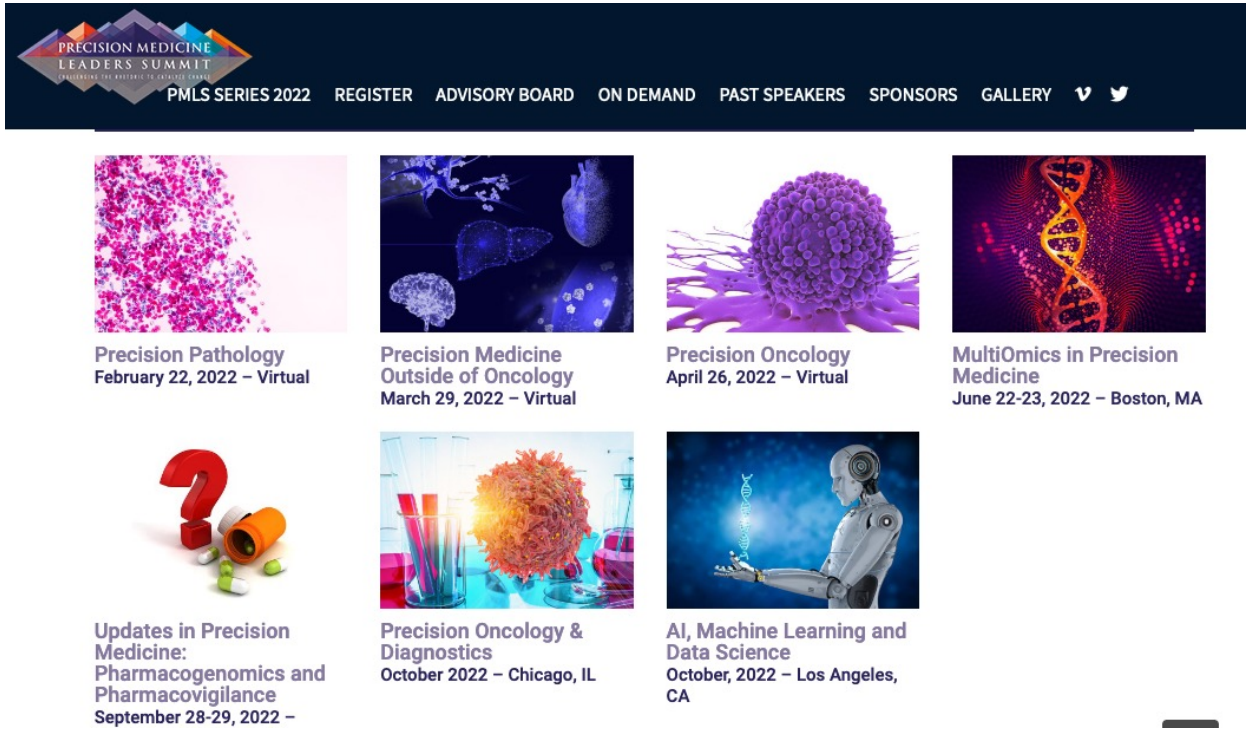
Upcoming Events



PMLS Virtual Series 2022 – Precision Pathology

To register **Click Here**

February 22, 2022



Next month's Steering Committee

- Wednesday
- February 23, 2022
- at 3:00-4:00PM ET