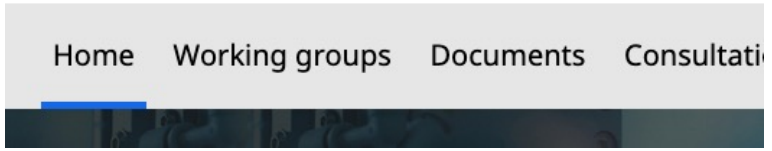
Monthly Steering Committee Meetings

February 23 2022 3-4PM ET

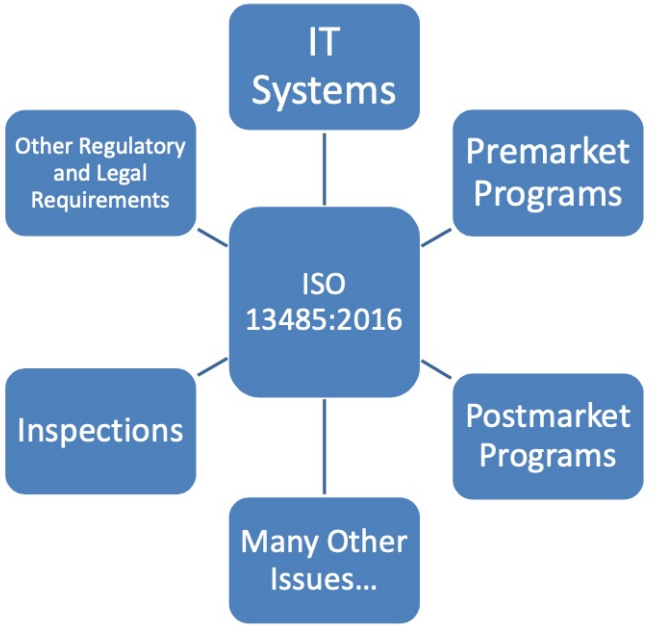
Pathology Innovation Collaborative Community



FDA QMS harmonization plan

- The U.S. Office of Information and Regulatory Affairs (OIRA) has completed a review of an FDA proposed rule about harmonizing and modernizing the regulation of medical device quality systems.
- AIM: **reduce compliance and recordkeeping burdens** on device manufacturers by bringing U.S. quality system requirements in line with standards that have been internationally adopted, called ISO 13485:2016
- Of note OIRA = part of the White House Office of Management and Budget
- OIRA declared the proposal as consistent with the principles
  - = executive order, planning etc will follow

Impacts to FDA



07:06 Request control Leave

Recording and transcription have started. By attending this meeting, you consent to being included. Privacy policy Dismiss

Division of Imaging, Diagnostics, and Software Reliability, OSEL/CDRH

Director, Aldo Badano
- Deputy Dir, Nicholas Petrick
- (s) Deputy Dir, Jana Delfino
- Assistant Dir, Kenny Cha
- Assistant Dir, selected

OUTPUTS
- 200 publications (2021)
- 560 reviews (2021)
- Tools/code (github)
- Community involvement

MANAGE MENT

TALENT
- 45 FTEs + 22 ORISE
- (+10 FTE/+11 ORISE since 2021)

RESEARCH AREAS
- Medical Imaging and Diagnostics
- Artificial intelligence and machine learning
- Digital Pathology
- Medical extended reality

FACILITIES
FDA White Oak campus
Lab space 15,000 ft²

OSEL Accelerating patient access to innovative, safe, and effective medical devices through best-in-the-world regulatory science A Badano, Director/DIDSR 4

Saltz, Joel
Badano, Aldo G
Garcia, Victor * (Guest)
YB
+19
Balagurunat...
Garcia, Victor * (Guest)

Opportunities and mechanisms

ORISE TRAINING FELLOWSHIPS FOR STUDENTS AND FACULTY

STIPEND DIRECT-TO-FELLOW OR THROUGH INSTITUTION

STIPEND LEVELS SET BY THE OFFICE BASED ON CV, SOMEWHAT FLEXIBLE

4-6 WEEKS ONBOARDING

INITIAL PERIOD CAN EASILY BE EXTENDED

FDA U.S. FOOD & DRUG ADMINISTRATION

QUESTIONS?

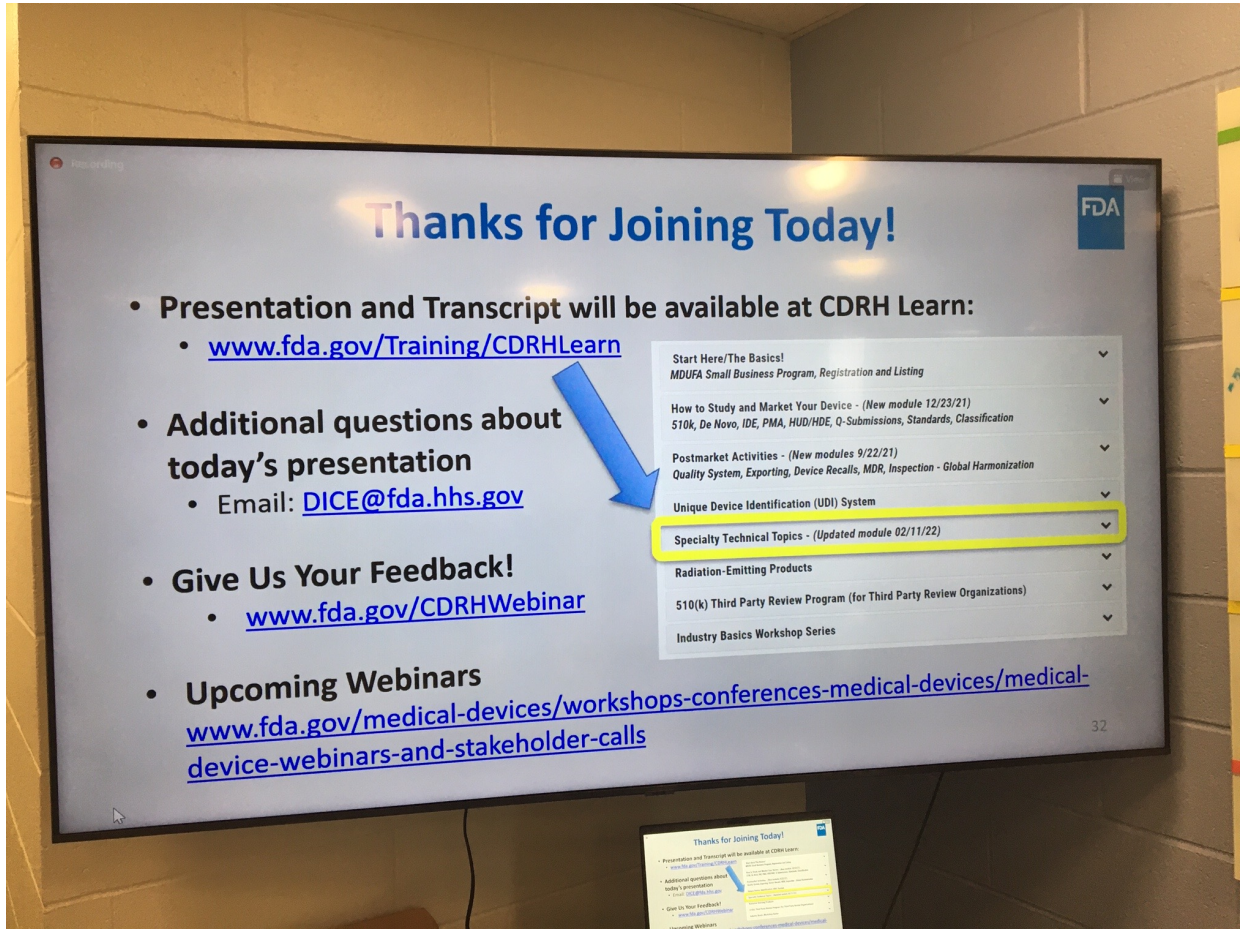
Project Contact List

Berkman Sahiner (Berkman.sahiner@fda.hhs.gov)

Weijie Chen (weijie.chen@fda.hhs.gov)

Ravi Samala (ravi.samala@fda.hhs.gov)

Transition Guidance for COVID-19 Devices



WEBCAST

Webinar on Draft Guidances on Transition Plans for COVID-19 Related Medical Devices

FEBRUARY 22, 2022

Share | Tweet | Linkedin | Email | Print

On This Page

- Meeting Information

Date: February 22, 2022

Time: 1:00 PM - 2:30 PM ET

Annual report

Collaborative Communities section

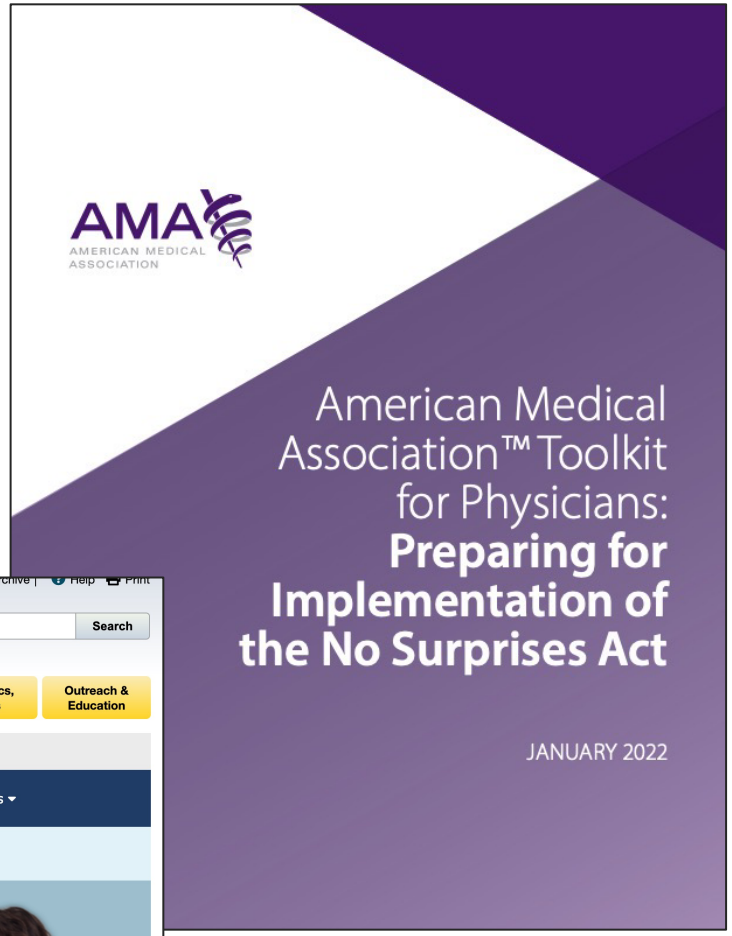
PIcc is mentioned

☺

No surprise act

On Dec. 27, 2020, the No Surprises Act (NSA) was signed into law as part of the Consolidated Appropriations Act of 2021

Access an initial toolkit (PDF) for physicians on implementation of the No Surprises Act (NSA). Many of the provisions of the NSA take effect on Jan. 1 and this document provides guidance on several of those provisions.



ISPOR abstract: not accepted

Health Data Use and Privacy Commission Act

Introduced

Tackles some of the problems discussed in the P3 project

Support from several Organizations

February 9, 2022

Senator Bill Cassidy
520 Hart Senate Office Building
Washington, DC 20510

Senator Tammy Baldwin
709 Hart Senate Office Building
Washington, D.C. 20510

Dear Senators Cassidy and Baldwin,

We write to thank you for your leadership in introducing the Health Data Use and Privacy Commission Act. The Commission established by this bill will make recommendations to Congress to help modernize health data use and privacy policies to ensure clear, consistent, and reliable patient protections while simultaneously ensuring health data gets where it needs to go to improve care and outcomes.

As the nation continues to adopt new and evolving technologies that surround everyday life and digitize nearly every interaction we have, personal privacy has never been a more important issue for policymakers. Congress is considering comprehensive privacy reform – and we support these efforts – but most of these conversations are focused on consumer technology and data. Health data is either carved out of these proposals or included in a new category of "consumer health data" which could lead to many entities being subject to duplicative requirements. The Health Insurance Portability and Accountability Act (HIPAA) law that led to today's HIPAA Privacy Rule was passed over 25 years ago, and while HIPAA is still functioning well, it does not address the growing concerns regarding third-party applications or other technologies accessing health data that fall outside of HIPAA's reach. Providers, health plans, and other covered entities and their business associates covered by the Privacy Rule as well as the patients they serve need clarity and consistency in health data privacy and use rules.

Given the advancements Congress has made in improving the interoperability of health care information and systems, your efforts to ensure robust consideration of health care data and privacy through the Health Data Use and Privacy Commission will provide useful perspective to the ongoing privacy debate. Secure and private health information should not be the enemy of medical innovation, clinical process improvement, or public health response. Careful consideration of these issues by the commission will inform policy makers to achieve the necessary balance of data liquidity and confidentiality necessary for a highly functional and trusted health system.

According to the International Association of Privacy Professionals (IAPP), "state-level momentum for comprehensive privacy bills is at an all-time high."[1] The patchwork of proposals across all 50 states could lead to further complexity and compliance burdens. According to the Information Technology and Innovation Foundation, should all 50 states pass privacy legislation in the absence of a federal law, compliance costs "could exceed $1 trillion over 10 years, with at

[1] https://iapp.org/resources/article/us-state-privacy-legislation-tracker/

TAM22183 F4P S.L.C.

117TH CONGRESS
2D SESSION

S. _____

To establish the Commission for the Comprehensive Study of Health Data Use and Privacy Protection.

IN THE SENATE OF THE UNITED STATES

Mr. CASSIDY (for himself and Ms. BALDWIN) introduced the following bill; which was read twice and referred to the Committee on

A BILL

To establish the Commission for the Comprehensive Study of Health Data Use and Privacy Protection.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Health Data Use and Privacy Commission Act".

SEC. 2. FINDINGS; RULE OF CONSTRUCTION; SENSE OF CONGRESS.

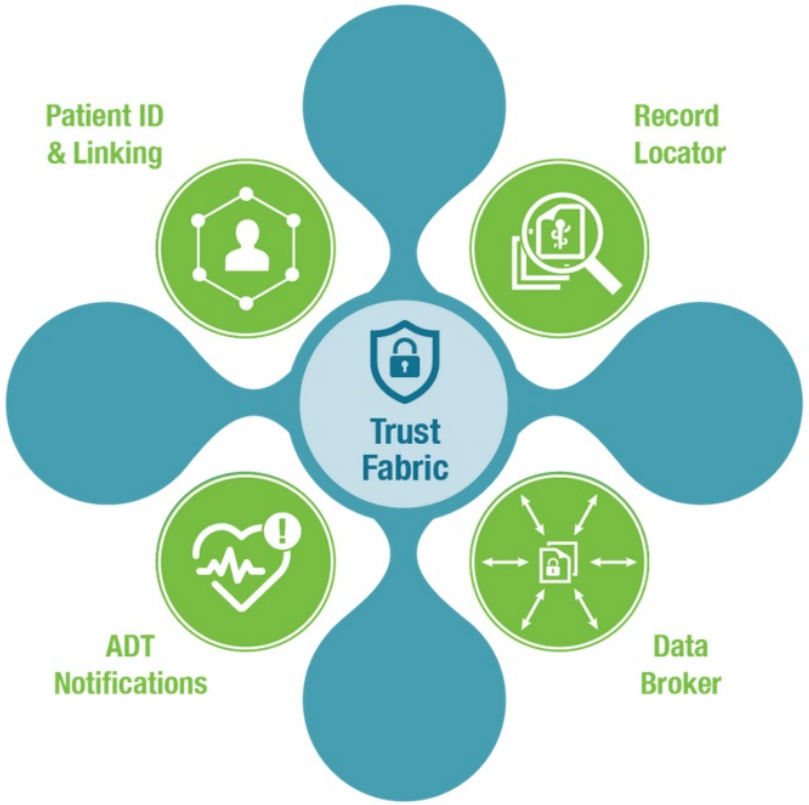
(a) FINDINGS.—Congress finds the following:

(1) The people of the United States are increasingly concerned about their civil liberties and the

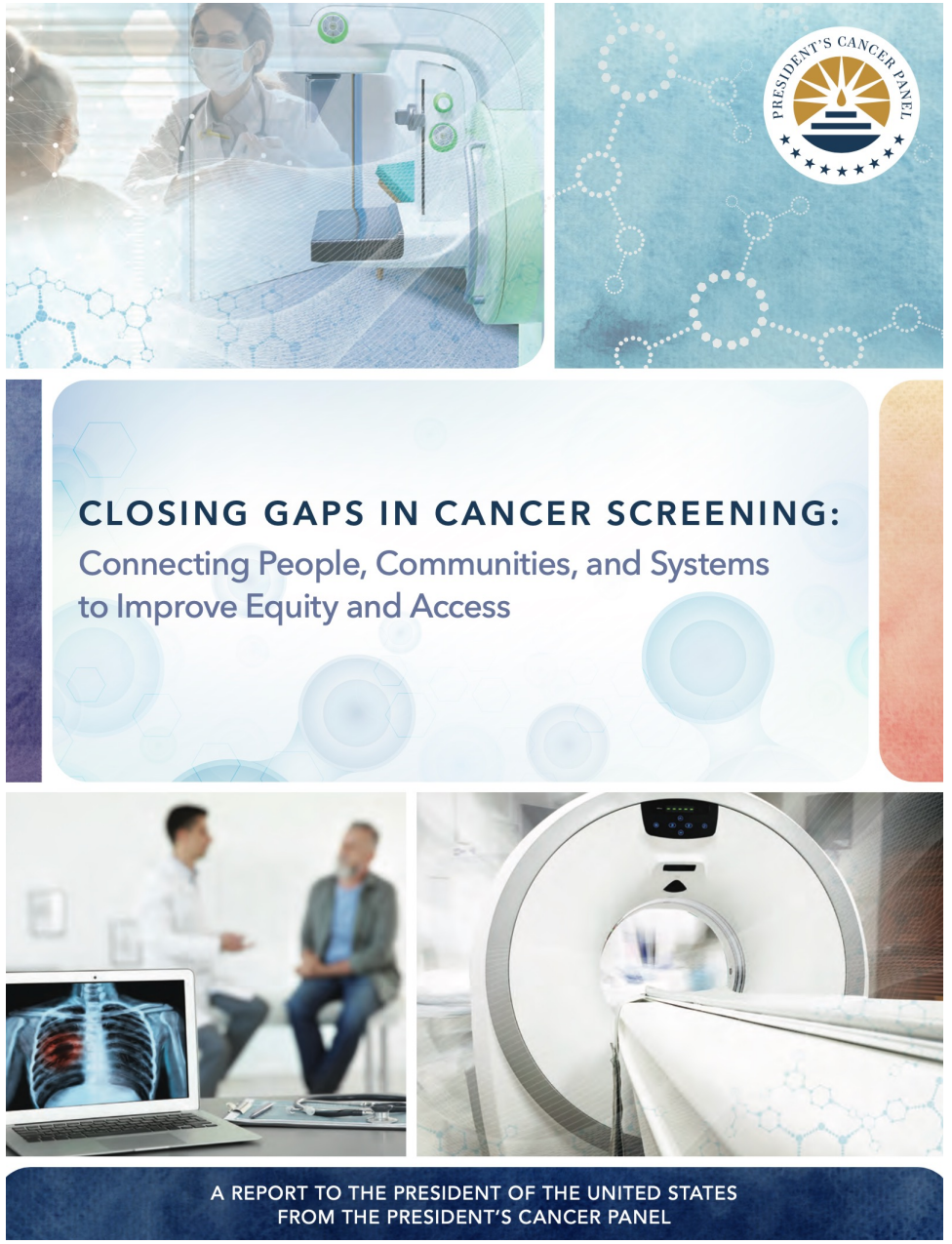
CommonWell Health Alliance

- aim to enable health care providers to manage patient identity, link patients across organizations, and facilitate secure data access and exchange beyond one's own system or community

- Reaching out ok?



Closing Gaps in Cancer Screening



Patient Advocacy

FOCR whitepaper; webinar 2/22

FRIENDS of CANCER RESEARCH A FRIENDS OF CANCER RESEARCH WHITE PAPER

Expedited Development of Diagnostics for Therapies Targeting Rare Biomarkers or Indications

Introduction

Drug and diagnostic co-development has traditionally occurred

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Table 1: Proposed Minimum Requirements to Support Use of Tests Detecting Rare Variants

Performance Characteristic	Minimum Requirement*
Concordance (Sensitivity, specificity, accuracy)	30 biomarker negative samples A range up to 30 biomarker positive# samples If possible 6 known positives (confirmed using an orthogonal method)
Limit of Detection	1 known positive* sample in a serial dilution series with at least 3 replicates at each dilution step
Precision	Repeatability across operators, reagent lots, days, instruments using 2 positive samples per variant type, with one at 1.5x LOD and one at 2x LOD
Limit of Blank	5-10 replicates across 2-3 healthy donor samples using the same sample type

**Requirements and number of samples should be guided by the complexity and prevalence of the biomarker being detected*

#Can be a contrived sample

FOCR whitepaper; webinar 2/22

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FRIENDS of CANCER RESEARCH

A FRIENDS OF CANCER RESEARCH WHITE PAPER

Expedited Development of Diagnostics for Therapies Targeting Rare Biomarkers or Indications

Introduction

Drug and diagnostic co-development has traditionally occurred in a manner by which one drug is accompanied by one diagnostic test to sufficiently characterize the safety and efficacy of the drug, while contemporaneously demonstrating the analytical and clinical validity of the diagnostic test assessing the biomarker status and of the responding patients in a clinical trial. For rare biomarkers or indications, this approach may not sufficiently leverage opportunities to expedite development for therapies and balance the need for efficient development of a companion diagnostic (CDx). The field of oncology has progressed substantially with an improved understanding of the biology of cancer, which has coincided with the availability of next generation sequencing (NGS) technologies that can query many biomarkers in one test. In cancers where NGS can be employed to assess biomarker status, these advances make the traditional one drug-one test approach to development of targeted therapies less ideal and poorly aligned with clinical and laboratory practice and patient needs.

New drug development follows the typical investigational new drug (IND) processes for clinical development, and Study Risk Determination (SRD) is typically conducted to determine whether FDA investigational device exemption (IDE) approval is required for the use of an unapproved diagnostic test in the clinical study. Although local testing (e.g., tests performed at a lab affiliated with the patient's treatment facility using a laboratory

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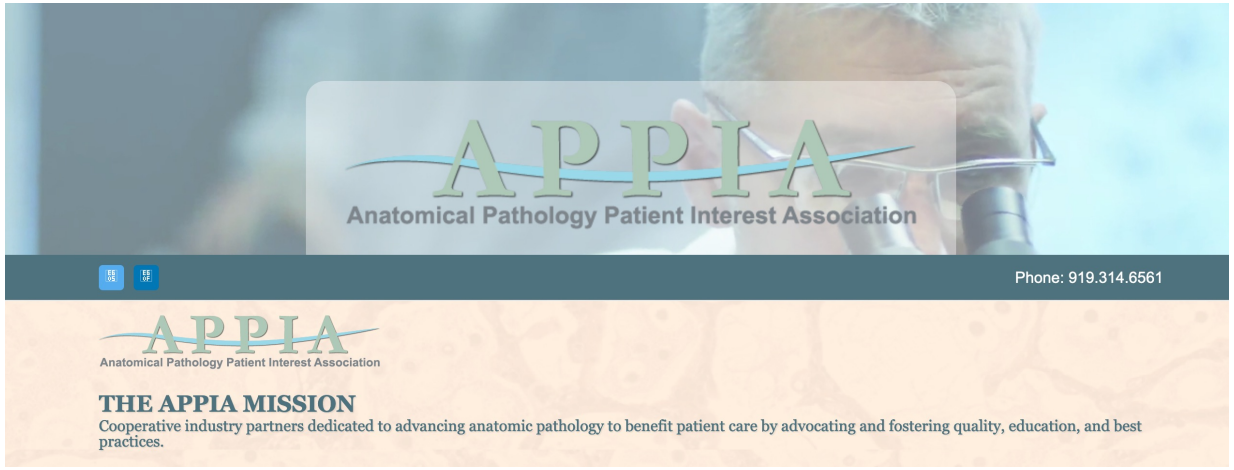


Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	
14	15	16 **overview**	17	18 overview to APPIA	19	20	Project Overview
21	22	23 PIcc	24	25 **APPIA Board**	26	27	
28	1	2 **Development**	3	4	5	6	
7	8	9 **Review / Finalize**	10	11 share website + proposal	12	13	
14	15	16	17	18	19	20 **APPIA Board**	"project outline"
21	22	23	24	25	26	27	
28	29	30					

Pre-analytics projects

- Review existing material
- Next pre-analytics meeting on Wednesday 3/2 at 1-2PM ET
- Selection of project proposal
- To APPIA
- Follow-up next Steering Committee

Pre-Analytics

The workgroup is placing emphasis on pre-analytical variables. The workgroup emphasizes the need to standardize human factors to create comparable samples from lab-to-lab for use in algorithmic/ML applications. Human factors are key determinants of pre-analytic variability (e.g., staining intensity, control slides, staining techniques, fixing/mounting, scoring, etc.). The group is trying to create a set of standardized guidelines and tools that offer protocols, instructions, definitions, and examples to a) establish valid scientific evidence that enables reliable assessment of pre-analytical variables, and b) provides a roadmap towards generalizability of AI/ML applications.

Project Proposals

Featured Papers

Artificial intelligence assistance significantly improves Gleason grading of prostate biopsies by pathologists

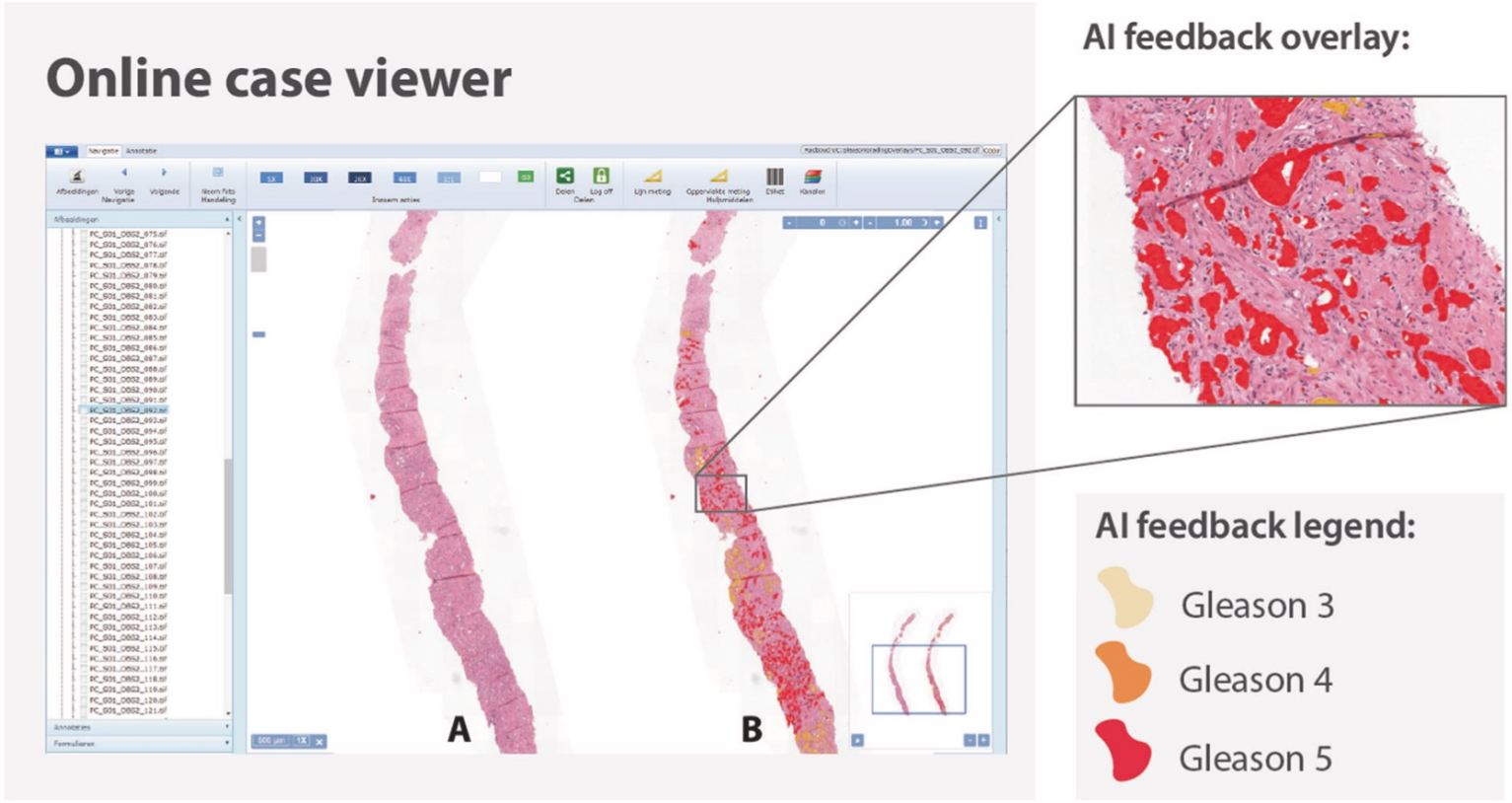
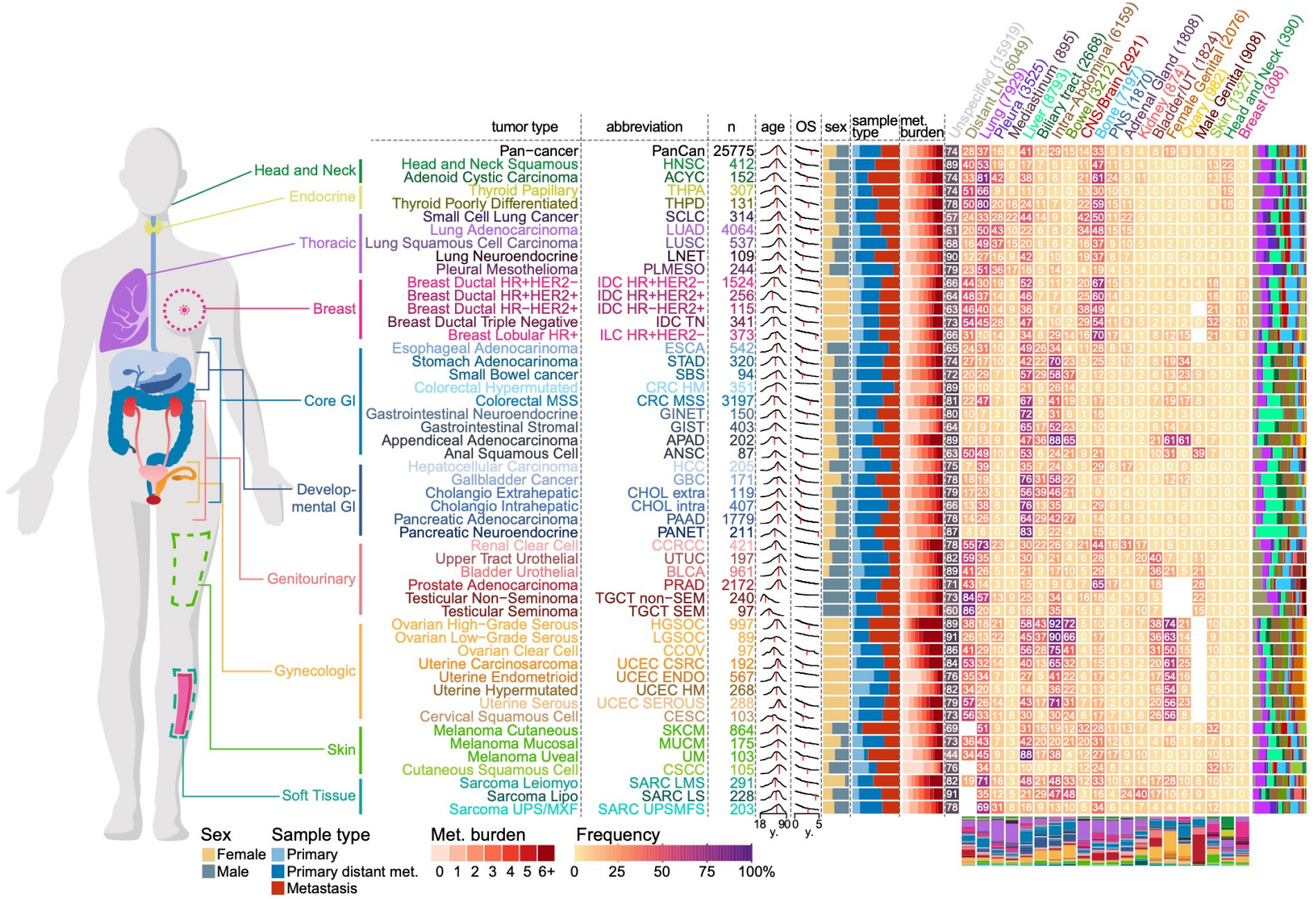
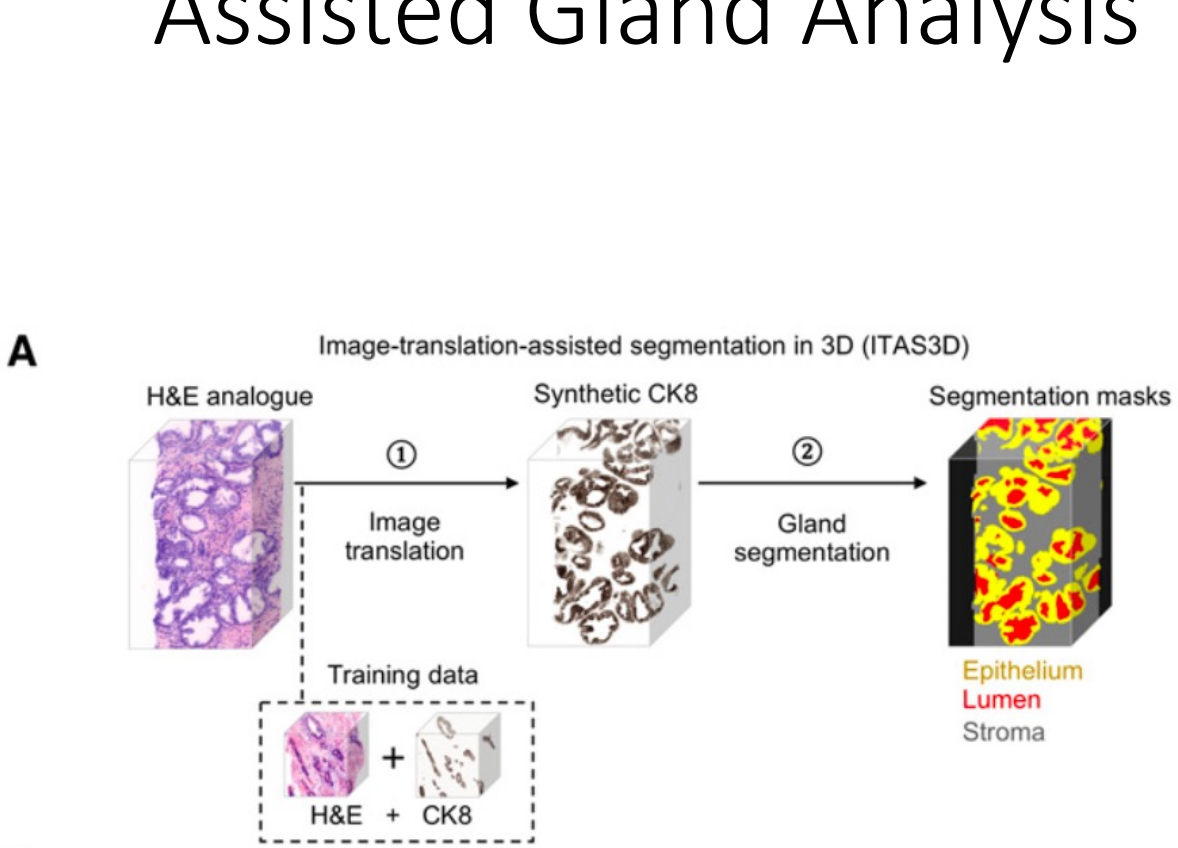


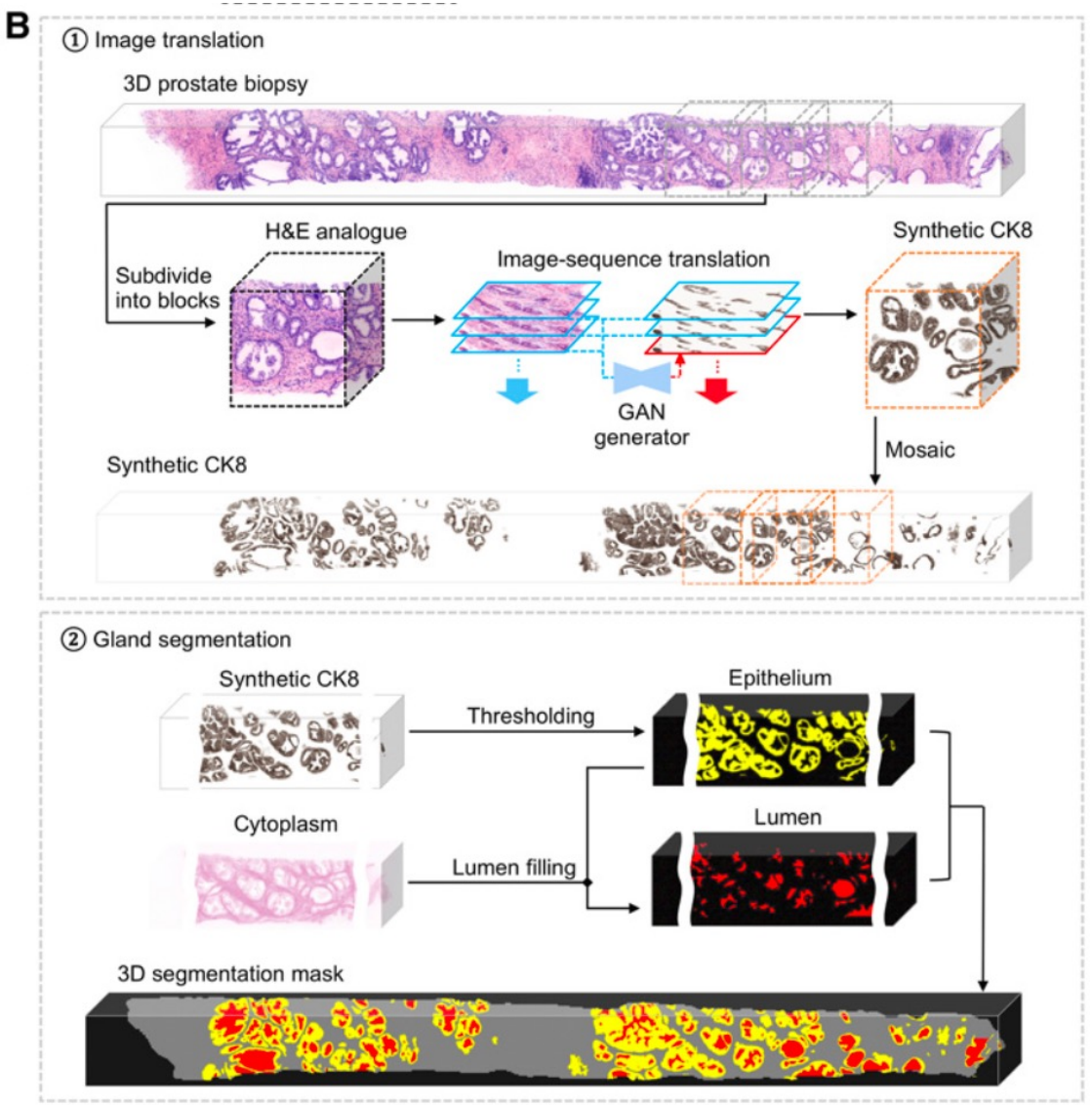
Fig. 1 Overview of the viewer used in the observer experiment. Both the original biopsy (**a**) and the biopsy with the AI overlay (**b**) are presented to the pathologist. Each individual tumor gland is marked by the deep learning system in the overlay. The case-level grade group was supplied to the panel as part of their (separate) grading form.

Genomic characterization of metastatic patterns from prospective clinical sequencing of 25,000 patients



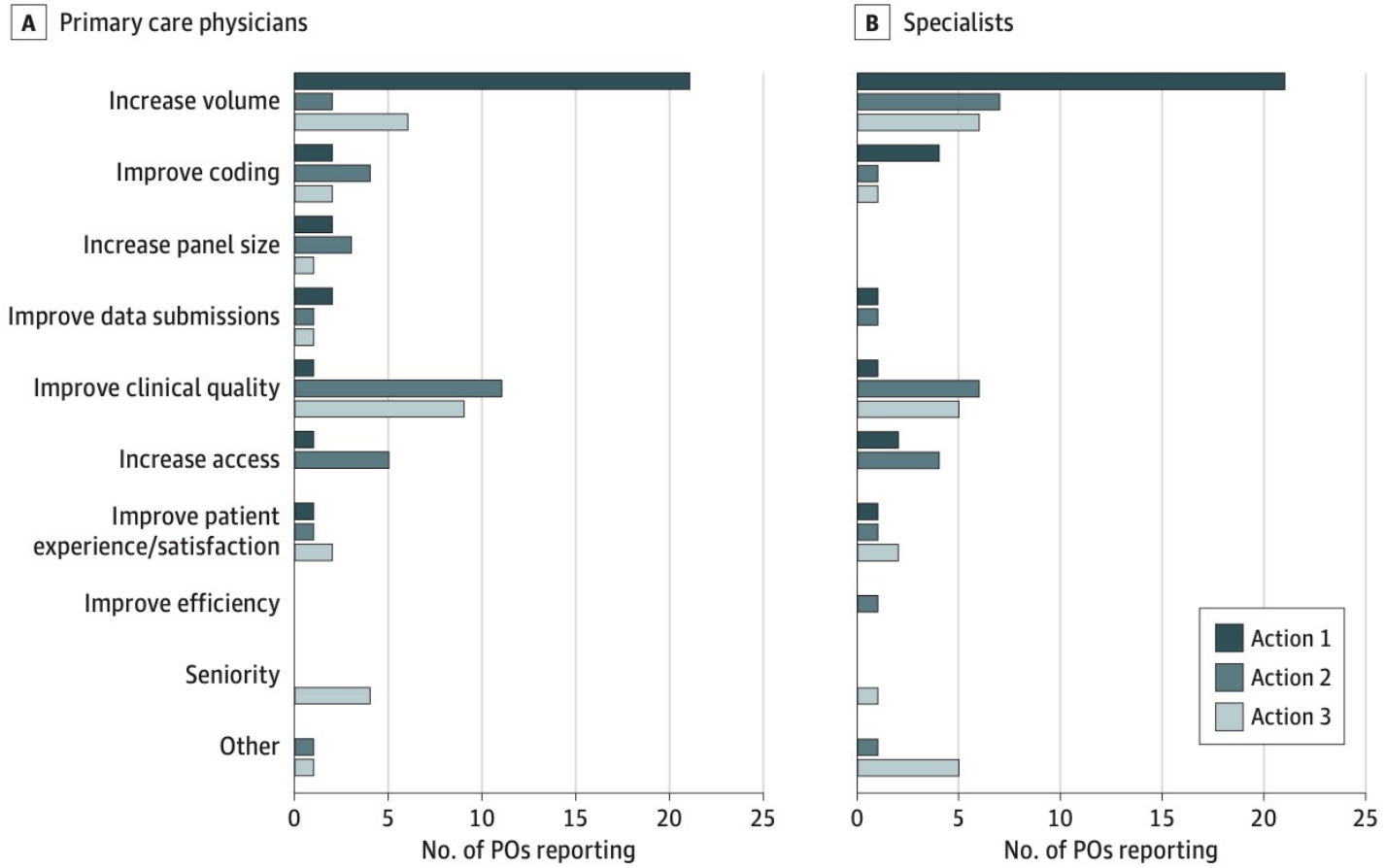
Xie et al. Prostate Cancer Risk Stratification via Nondestructive 3D Pathology with Deep Learning–Assisted Gland Analysis





Reid et al. Physician Compensation Arrangements and Financial Performance Incentives in US Health Systems

Figure 1. Top 3 Actions Physicians Can Take to Increase Compensation



POs indicates physician organizations.

von Stillfried et al. First report from the German COVID-19 autopsy registry

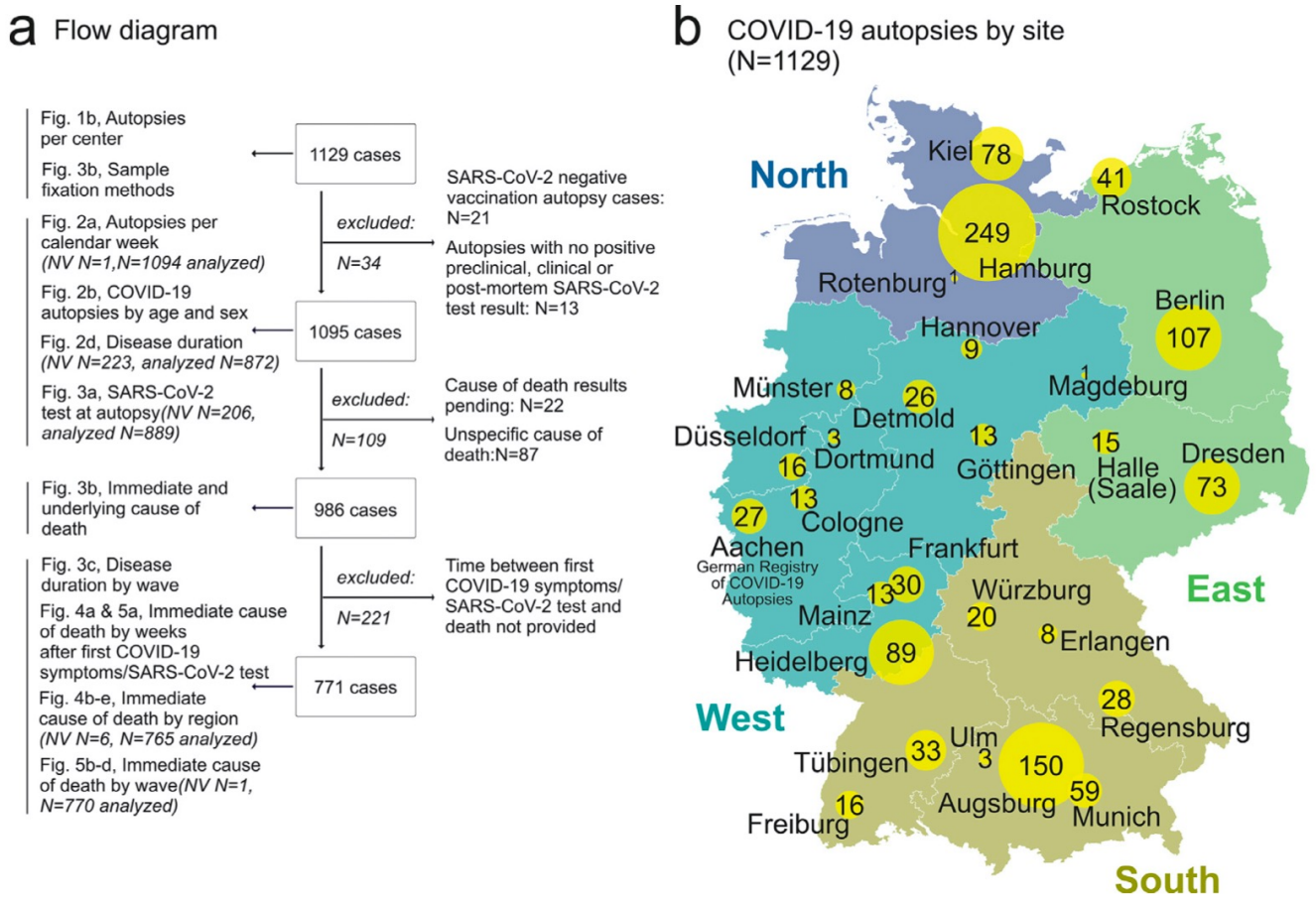


Figure 1. a) Flow diagram of included and excluded cases. b) COVID-19 autopsies per site. From N=1129 autopsies, contributed by N=29 university and non-university autopsy centers in N=27 cities, N=1095 autopsy cases were eligible for analyses. (Map source: Map Data from OpenStreetMap. This data is available under the Open Database License and under Creative Commons Attribution-Share Alike 2.0 license.)

NV = no value

Smit et al. Quality control of whole-slide images through multi-class semantic segmentation of artifacts

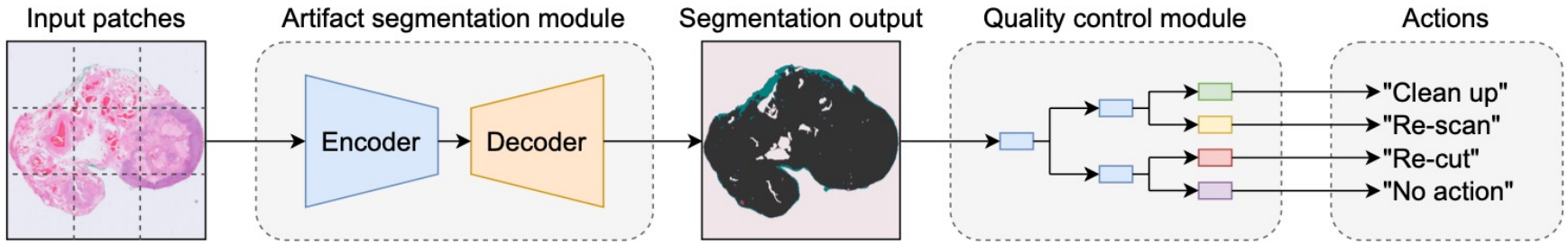


Figure 1: Overview of the proposed quality control framework.

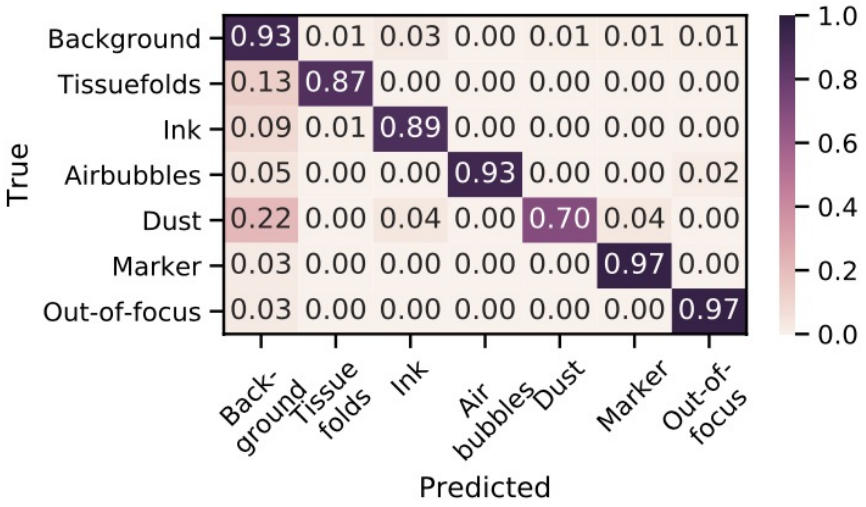


Figure 2: Pixel-level confusion matrix for classification of artifacts on the test set.

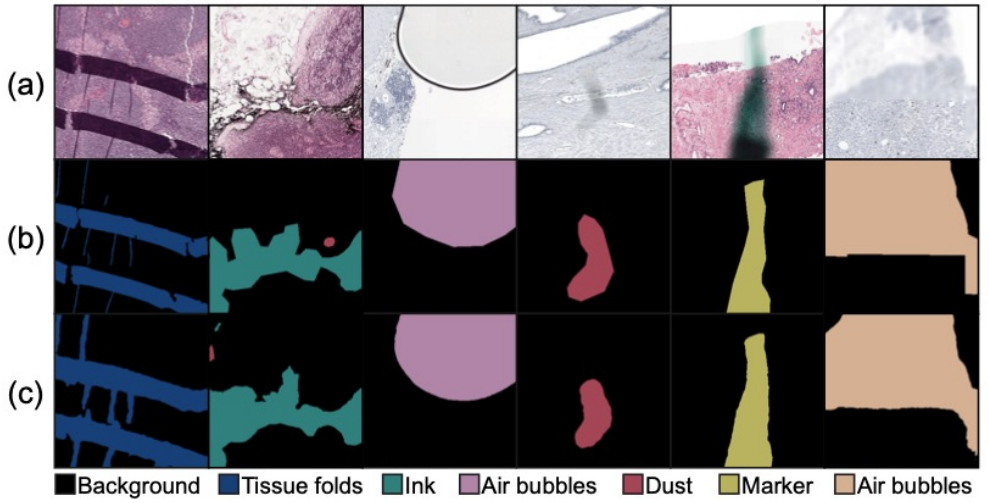


Figure 3: Qualitative results on the test set. (a) Image patches. (b) Ground truths. (c) Predictions.

Gallas et al. FDA fosters innovative approaches in research, resources and collaboration

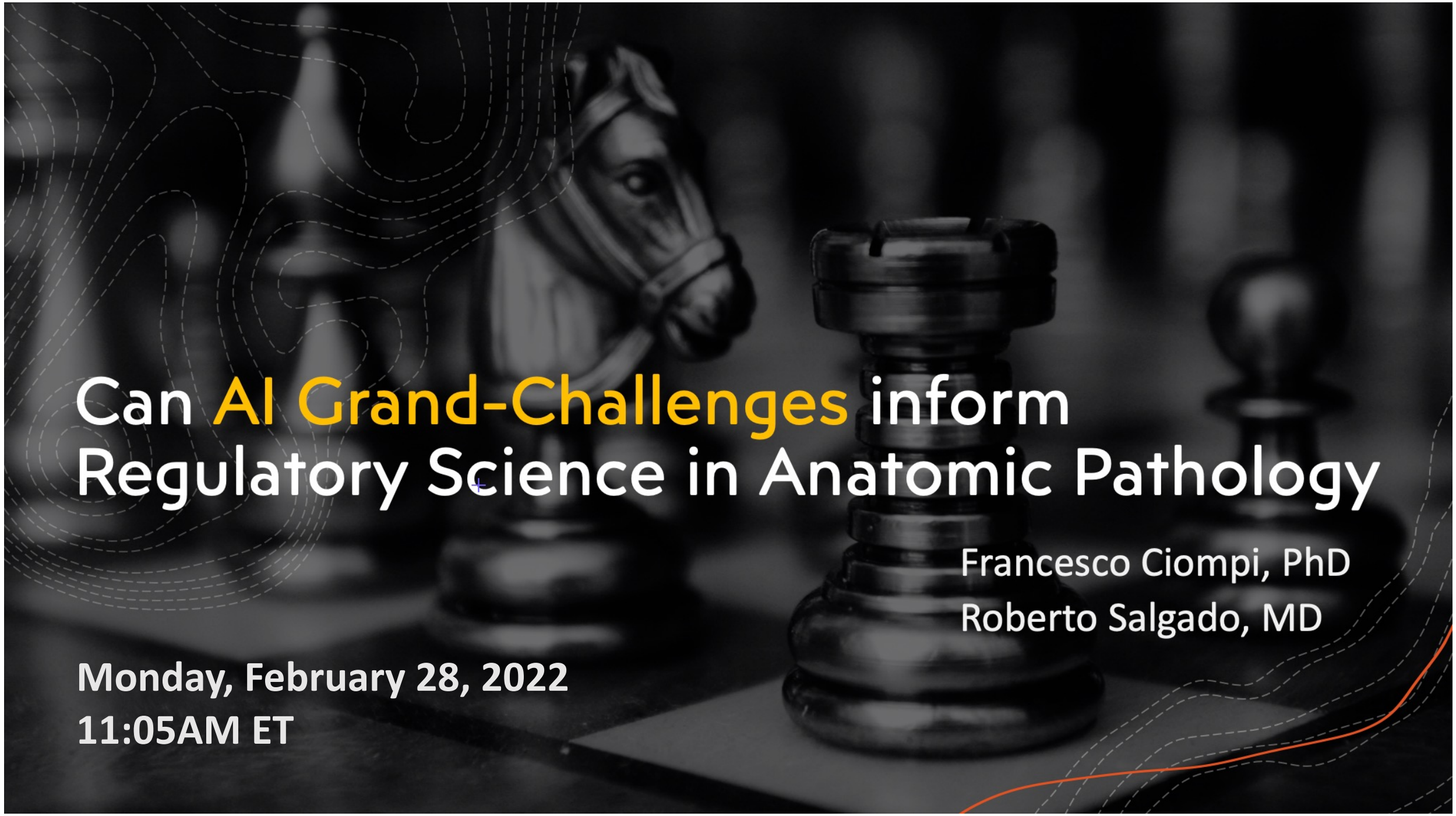
Brandon D. Gallas[1]✉, Aldo Badano[1]✉, Sarah Dudgeon[2,3], Katherine Elfer[1], Victor Garcia[1], Jochen K. Lennerz[4], Kyle Myers[5], Nicholas Petrick[1] and Ed Margerrison[6]✉

fda.hhs.gov; *edward.margerrison@fda.hhs.gov*

Published online: 23 February 2022
https://doi.org/10.1038/s42256-022-00450-2

References

1. *Nat. Mach. Intell.* **2**, 729 (2020).


Can AI Grand-Challenges inform
Regulatory Science in Anatomic Pathology
Francesco Ciompi, PhD
Roberto Salgado, MD
Monday, February 28, 2022
11:05AM ET

WEBCAST

Webinar - Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation - Final Guidance

MARCH 1, 2022

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On This Page

Date: March 1, 2022

Time: 1:00 PM - 2:30 PM ET

Content current as of:
01/25/2022

USCAP

- 3/19-3/24 USCAP
- Saturday night
- 21:00
- Mariott LA Live
- Bar

Next steering committee meeting