Monthly Steering
Committee Meetings

May 25
2022 3-4PM ET

Pathology Innovation Collaborative Community


LIVE


Innovate, Connect, Inspire
PI Summit May 9-12, 2022
Pittsburgh, PA

CPIM: WSI for nonclinical development

Implementing WSI in the regulated nonclinical development of pharmaceuticals and chemicals

Advancing Cancer Research Through Collaboration

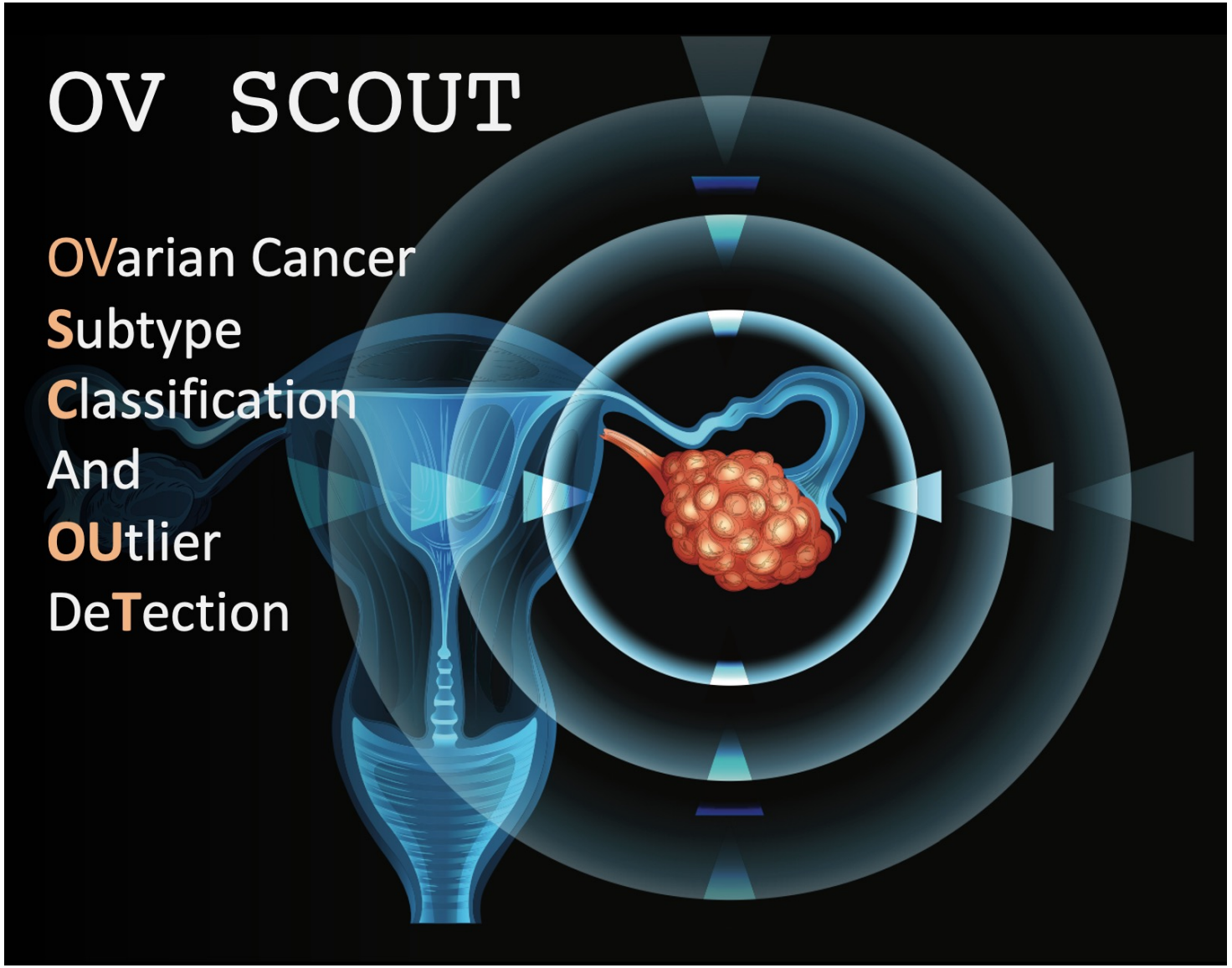
Upcoming meeting:

Wednesday, July 13 at 11AM ET

OV SCOUT

Upcoming meeting:

Tuesday, May 31 at 3PM ET



SEER 2.0

Upcoming Meetings:

Tuesday, May 24 at 3-3:45 PM ET ✓

Friday, May 27 at 1-1:45 PM ET

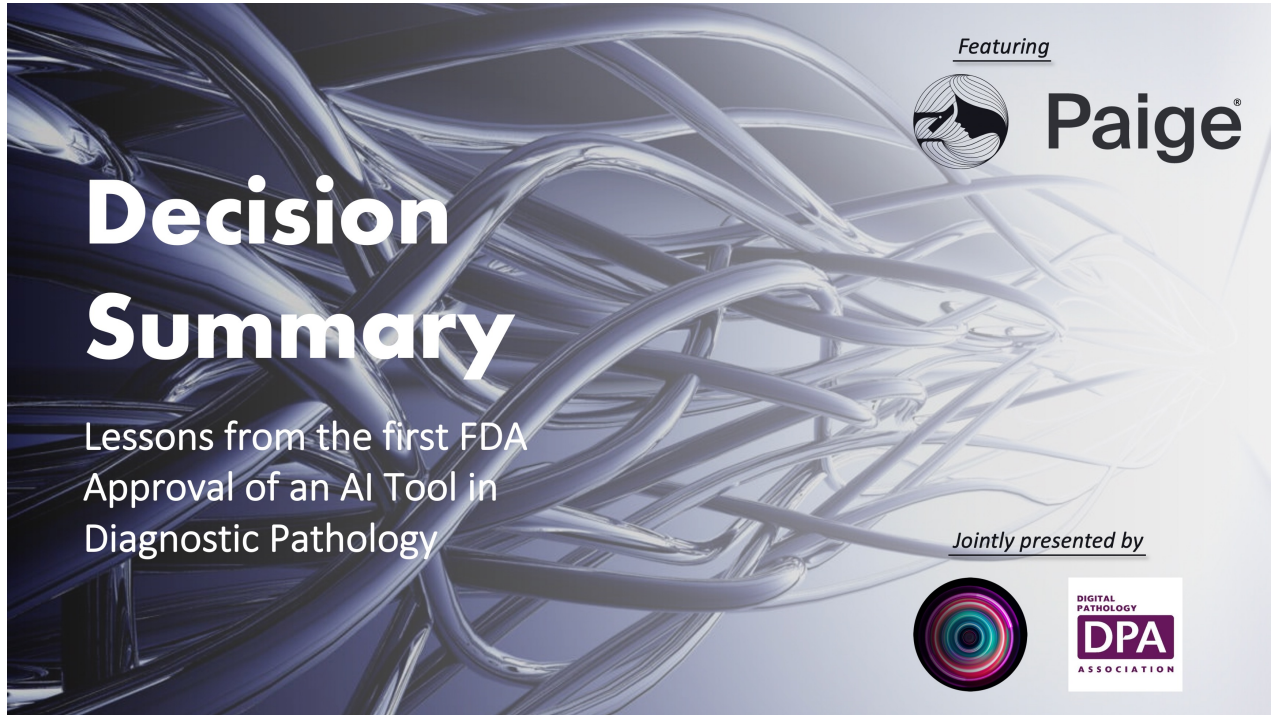
Friday, June 3 at 1-1:45 PM ET

Friday, June 10 at 1-1:45 PM ET

Planning phases…

Paige Decision Summary Event

- Presented in collaboration with DPA
- With participation by Paige
- Tentative date: June 22 at 10AM



Planning phases…

Sepsis Summit

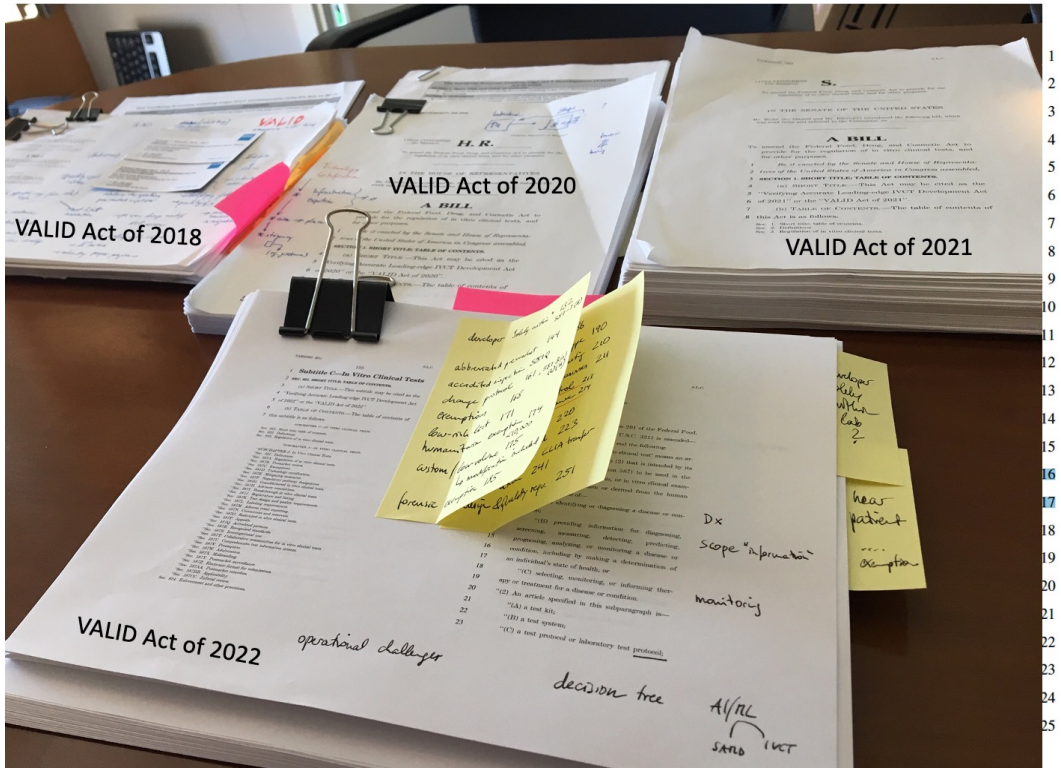
- In collaboration with recently launched Sepsis Innovation Collaborative
- In-person meeting
- Date TBD (tentative date June 24)

VALID Update

Food and Drug Administration Safety and Landmark Advancements Act (FDASLA)

FDA Issues Safety Warning Regarding Non-Invasive Prenatal Testing Raising Questions About the Future of FDA Regulation of LDTs

May 25, 2022
By Allyson B. Mullen & Jeffrey N. Gibbs & Gail H. Javitt —



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"(B) REMOVAL OF CLINICAL HOLD.—Any written request to the Secretary from the sponsor of an investigation that a clinical hold be removed shall receive a decision, in writing and specifying the reasons therefor, within 30 days after receipt of such request. Any such request shall include sufficient information to support the removal of such clinical hold.

["SEC. 587T. COLLABORATIVE COMMUNITIES FOR IN VITRO CLINICAL TESTS.

["(a) IN GENERAL.—]

["(1) For the purposes of facilitating community solutions and decision making with respect to in vitro clinical tests, the Secretary may participate in collaborative communities comprised of public and private participants that may provide recommendations and other advice to the Secretary on the development and regulation of in vitro clinical tests.]

["(2) A collaborative community under this section shall have broad representation of interested private and public-sector stakeholder communities and may include patients, care partners, academics, health care professionals, health care systems, payors, Federal and State agencies, entities responsible for accrediting clinical laboratories, inter-

CPT Codes AMA Digitization of slides

AMA AMERICAN MEDICAL ASSOCIATION

Proposed Panel Agenda
May 2022 CPT® Editorial Panel Meeting

Issues	Tabs	Deadline to Request Materials	Comments Deadline (Noon, CST)
All Non-Pathology Issues	**7-20, 32-64**	**April 21, 2022**	**April 28, 2022**
Path/Lab	**21-31, 44**	**March 11, 2022**	**March 18, 2022**

Tab #	Name	Code #	Request-Description
43	Cat II - Medication Adherence for Opioid Use Disorder	---------- ----------	**WITHDRAWN**
44	Cat III - Digital Pathology	● X018T ● X025T ● X019T ● X026T ● X020T ● X027T ● X021T ● X028T ● X022T ● X029T ● X023T ● X030T ● X024T	Establish codes X018T-X030T to report additional service requirements associated with digitizing glass microscope slides for primary diagnosis
45	Cat III - AI Analysis for Cardiac Function Services	● X044T ● X045T	Establish codes X044T, X045T, X046T, X047T to report artificial intelligence (AI) to ECG data for possible detection and autonomous generation

Updates from Truthing & Validation WG

CENTER FOR DRUG EVALUATION AND RESEARCH

What's New in Regulatory Science

FDA

Issue I - 2022

CDER Newsletter

IN PRESS

This section provides highlights from select CDER research publications. Click here to see the complete FDA publication list. Look up the Drugs section for CDER Publications.

A Bayesian population PBPK absorption modeling approach to support generic drug development

Through model building and simulations, CDER researchers demonstrate how PBPK modeling, enhanced by Bayesian methodology and vitro and in vivo information, can be used to inform decisions related to generic drug product development. Learn more.

Early antibody responses associated with survival in COVID19 patients

Using a highly sensitive multiplexed bead-based immunoassay, CDER investigators found that early appearance of anti-SARS-CoV-2 antibodies was associated with survival in patients hospitalized with COVID 19. Learn more.

Single in-line biomass probe detects CHO cell growth by capacitance and bacterial contamination by conductivity in bioreactor

CDER investigators have demonstrated the feasibility of using in line conductivity measurements for

Characterization of the therapeutic effect of antibodies targeting the Ebola glycoprotein using a novel BSL2-compliant rVSVΔG-EBOV-GP infection model

CDER researchers demonstrated that a mouse model suitable for biosafety level 2 laboratories can be used to

Retrospective analysis of clinical trial safety data for pembrolizumab reveals the effect of co-occurring infections on immune-related adverse events

Biologics targeting immune check-point proteins can cause adverse events, resulting in discontinued

UPCOMING EVENTS

Information on upcoming meetings, conferences, and workshops sponsored or co-sponsored by CDER, click here.

Some of the events are listed below:

1. April 26 and 27, 2022: FY 2022 Generic Drug Science and Research Initiatives Public Workshop
2. May 9 and 10, 2022: : Generic Drugs Forum 2022: The Current State of Generic Drugs
3. May 16 and 17, 2022: Pharmacokinetic Evaluation in Pregnancy- (Virtual)
4. May 16 and 17, 2022: FDA CDER & NIH NCATS Regulatory Fitness in Rare Disease Clinical Trials Workshop
5. June 3, 2022: Development Considerations of Antimicrobial Drugs for the Treatment of Uncomplicated Urinary Tract Infections (UTI) (Virtual)
6. June 29, 2022: FDA-CRCG (Center for Research on Complex Generics) Workshop on In Vitro Release Test (IVRT) and In Vitro/In Vivo Correlation (IVIVC) of Complex Generic Ophthalmic, Injectable, Implantable, and Inserted Products. Learn more.
7. October 27-28, 2022: FDA-CRCG Workshop on Using Model Integrated Bioequivalence (BE) Approaches in Complex Generic Product Development. Learn more.
8. November 3, 2022: FDA-CRCG Workshop on Evaluation of Cutaneous Pharmacokinetics to Facilitate Complex Generic Topical Product Development. Learn more.
9. December 6, 2022: FDA-CRCG Training on Excipients and Formulation Assessments of Complex Generic Products: Best Practices and Lessons Learned. Learn more.

CDER Newsletter

Proposal: Cell Free Working Group

Use of Circulating Tumor DNA for Early-Stage Solid Tumor Drug Development

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

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

For questions regarding this draft document, contact Julia Beaver (OCE) at 240-402-0489.

U.S. Department of Health and Human Services
Food and Drug Administration
Oncology Center of Excellence (OCE)
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)

May 2022
Clinical/Medical

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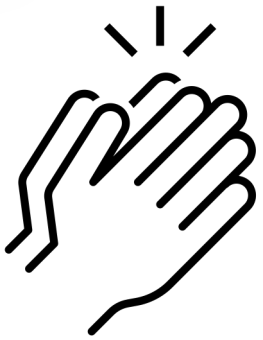
APPIA

Anatomical Pathology Patient Interest Association

Update: APPIA officially joined PIcc

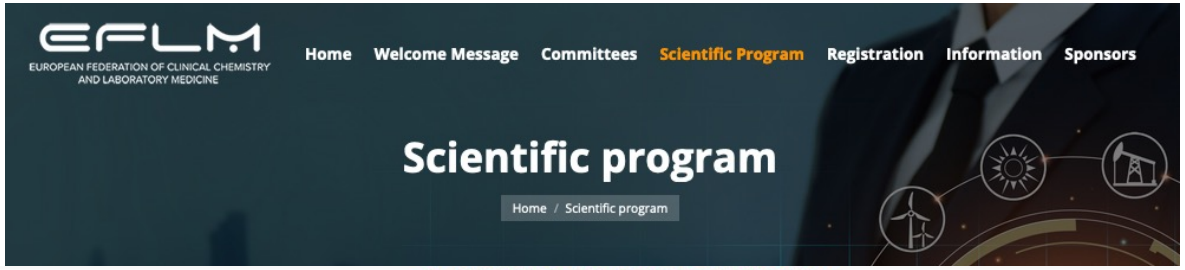


Collaboration on a protocol development project is in the works

PathML Presentation

June 6, 10AM ET

European Federation of Clinical Chemistry and Laboratory Medicine



3rd EFLM STRATEGIC CONFERENCE

Time zone: all times are indicated on Central European Time.

Wednesday, 25 May 2022

10:20-10:30 Welcome Address
Tomris Ozben *(EFLM, President, EFLM Strategic Conference, Chair)*

10:30-12:30 Session 1

Where is the MedLab industry headed in the next decade? Partnership model for efficient integration and adoption of em technologies and innovations (artificial intelligence, machine learning, advanced and integrative diagnostics) in the IVD landscape into Medical Laboratories.

Chairs: ***Sergio Bernardini*** *(IFCC, Emerging Technologies Division, Chair)*
Anna Carobene *(EFLM Task Group-Biological Variation Database, Member)*

• Introduction

• Rise of the machines – How AI could help making our profession more medical
Janne Cadamuro *(EFLM WG Preanalytical Phase, Chair)*

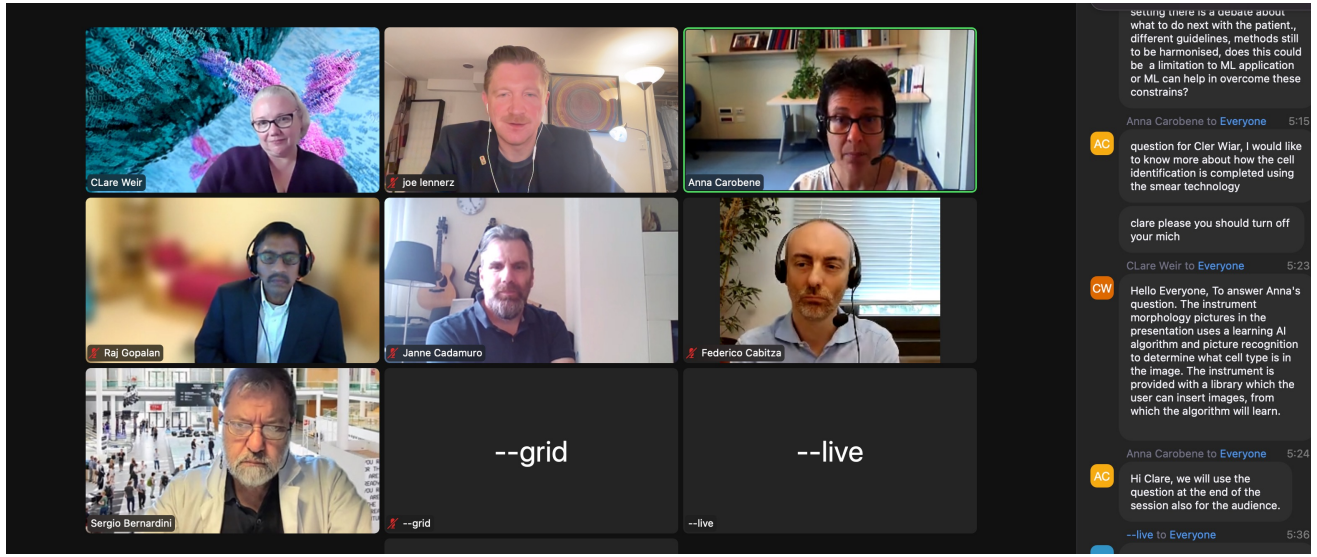
• Solutions in haemato-oncology: Exploring the patient's clinical pathway
Clare Weir *(Senior Expert & Scientific Marketing Manager in Clinical Flow Cytometry, Sysmex Europe)*

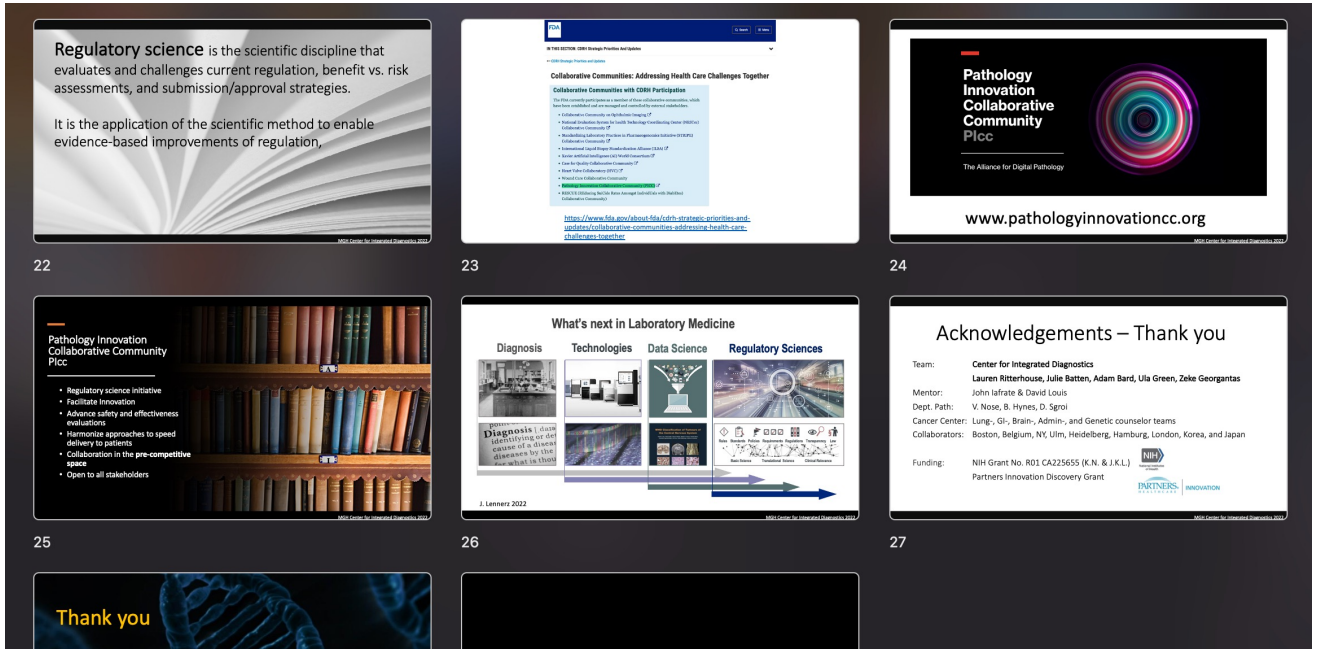
• The Crucial Role of Lab Diagnostics in Clinical Decision making in an era of Artificial Intelligence
Raj Gopalan *(Siemens Healthineers Diagnostics, Chief Medical Information Officer and Global Head of Clinical Decision Support)*

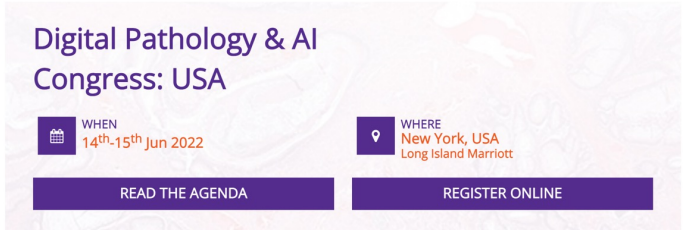
• With each passing day, I place less value on accuracy. Some ideas to go beyond accuracy in evaluating machine-learning AI syster
Federico Cabitza *(Associate Editor of International Journal of Medical Informatics; Human-Computer Interaction, University of Mi Bicocca)*

• The Importance of Regulation of AI/ML in the Laboratory
Jochen K. Lennerz *(Medical Director, Center for Integrated Diagnostics, Harvard Medical School)*

• Discussion







Events of interest

Next Steering Committee: Wednesday, June 29 3PM ET

Pathology Innovation Collaborative Community

PIcc

The Alliance for Digital Pathology