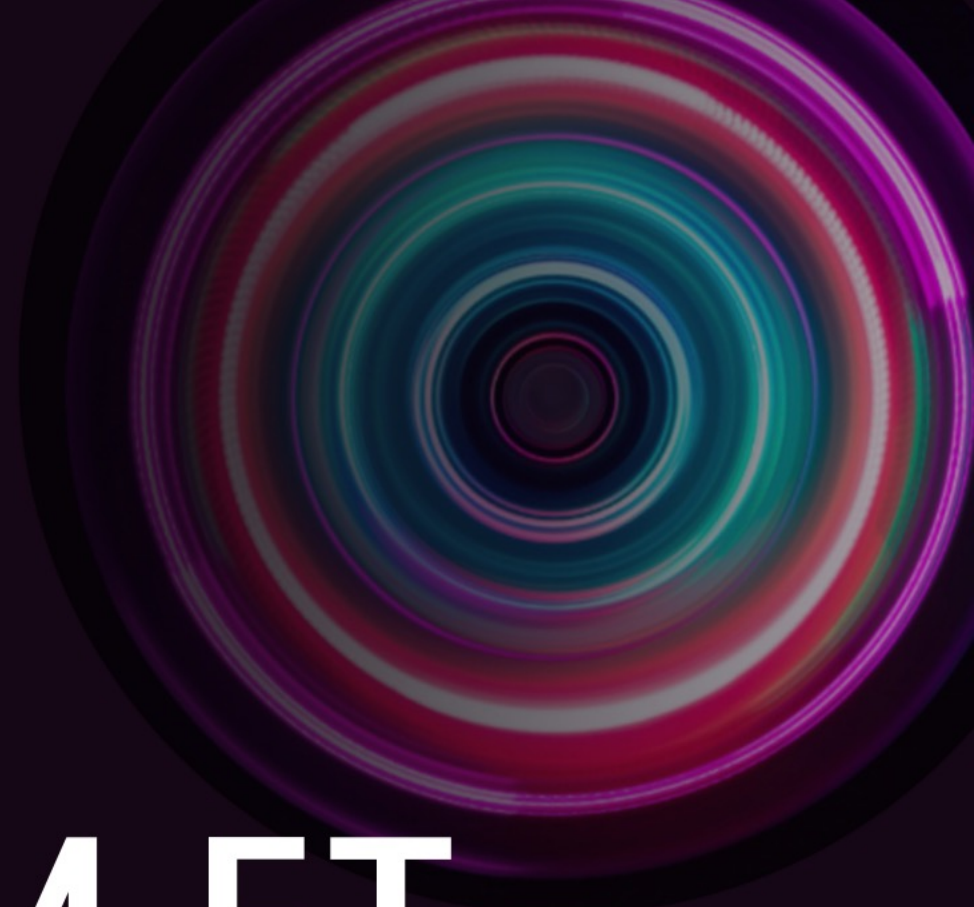


Monthly Steering
Committee Meetings

May 25
2022 3-4PM ET

Pathology Innovation Collaborative Community





Innovate, Connect, Inspire

PI Summit May 9-12, 2022
Pittsburgh, PA

by Ur

CPIM: WSI for nonclinical development

Implementing WSI in the regulated nonclinical development of pharmaceuticals and chemicals



FDA U.S. FOOD & DRUG
ADMINISTRATION
CENTER FOR DRUG EVALUATION & RESEARCH

Critical Path Innovation Meeting (CPIM)

Center for Drug Evaluation and Research (CDER)
Office of Translational Science (OTS)

Advancing Cancer Research Through Collaboration

Upcoming meeting:

Wednesday, July 13 at 11AM ET



Advancing Cancer Research Through Collaboration

Friends of Cancer Research (*Friends*) is working to accelerate policy change, support groundbreaking science, and deliver new therapies to patients quickly and safely.

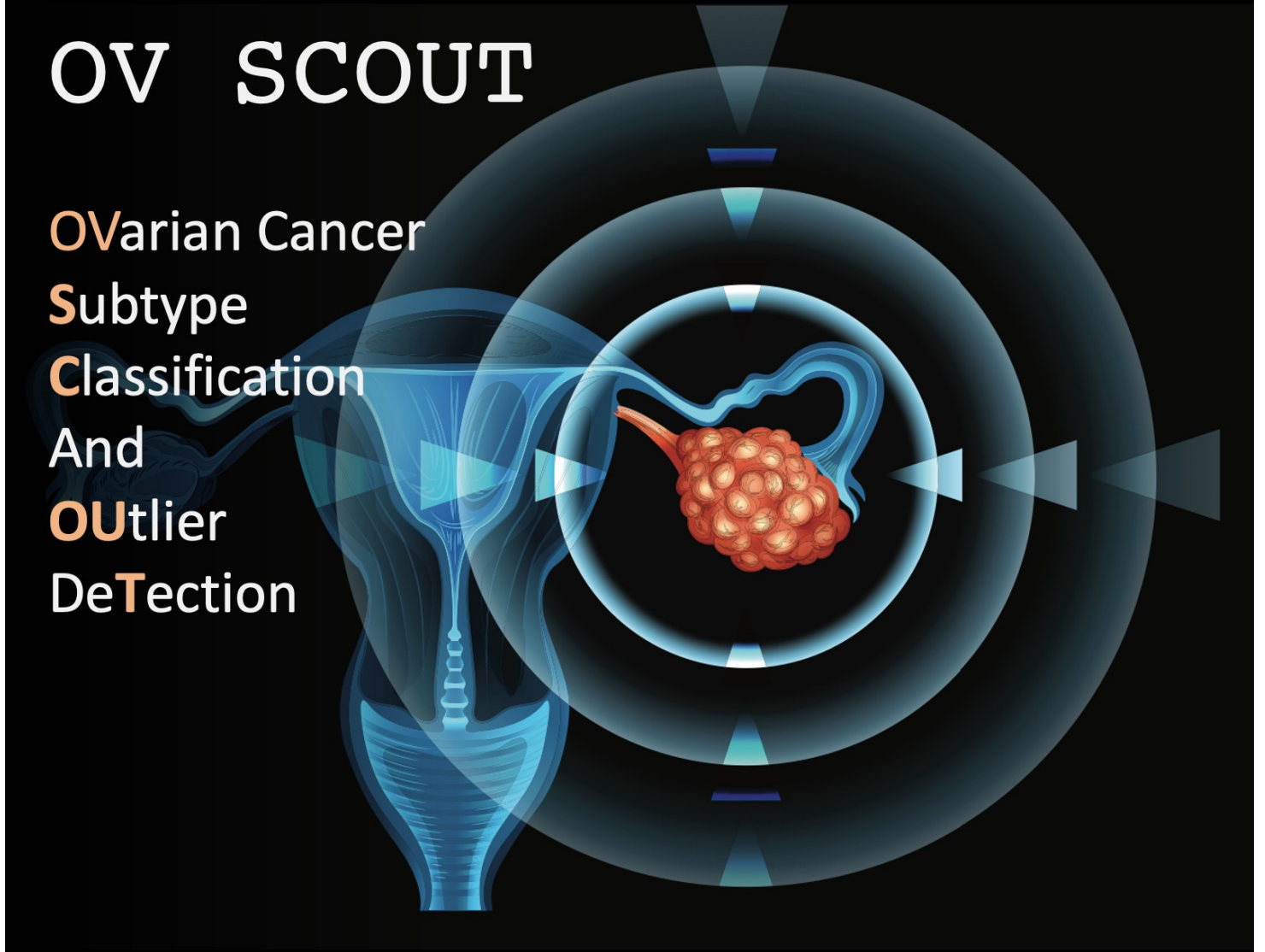
OV SCOUT

Upcoming meeting:

Tuesday, May 31 at 3PM ET

OV SCOUT

Ovarian Cancer
Subtype
Classification
And
Outlier
Detection



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

A background image for a slide featuring a microscope in the foreground and several red blood cells floating in the background. The text is overlaid on the right side of the image.

SEER 2.0

CANCER DIAGNOSTICS: CURRENT STATE TO FUTURE TRENDS

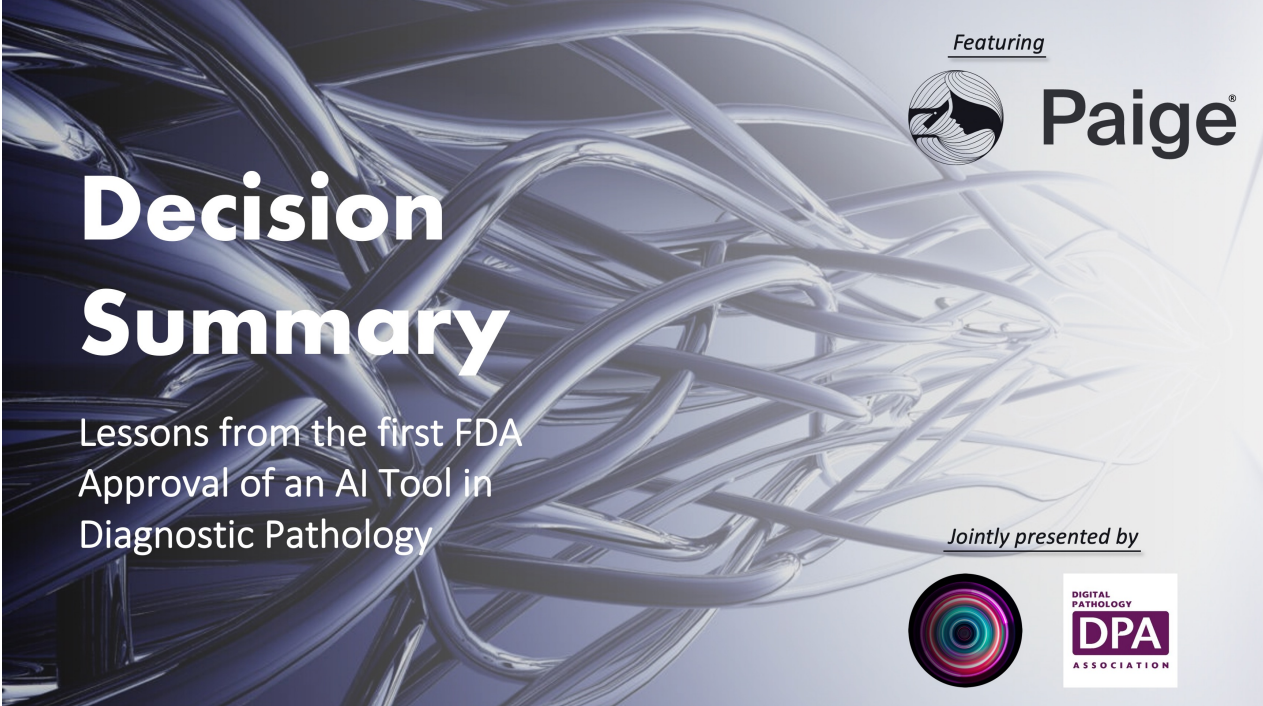
*Trends in adoption of emerging
technologies in cancer diagnostics*

 PATHOLOGY INNOVATION COLLABORATIVE COMMUNITY

Planning phases...


Paige Decision Summary Event

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



The poster features a background of blue, glowing, intertwined fiber-optic cables. The text is white and centered. At the top right, it says 'Featuring' above the Paige logo, which consists of a stylized hand holding a magnifying glass over a globe, followed by the word 'Paige' with a registered trademark symbol. The main title 'Decision Summary' is in a large, bold, sans-serif font. Below it, the subtitle 'Lessons from the first FDA Approval of an AI Tool in Diagnostic Pathology' is in a smaller font. At the bottom right, it says 'Jointly presented by' above two logos: a circular logo with concentric rings of purple, blue, and green, and the DPA Association logo, which is a purple square with 'DPA' in white and 'ASSOCIATION' in smaller white text below it.



Featuring

 Paige®

Decision Summary

Lessons from the first FDA
Approval of an AI Tool in
Diagnostic Pathology

Jointly presented by

Sepsis Summit

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

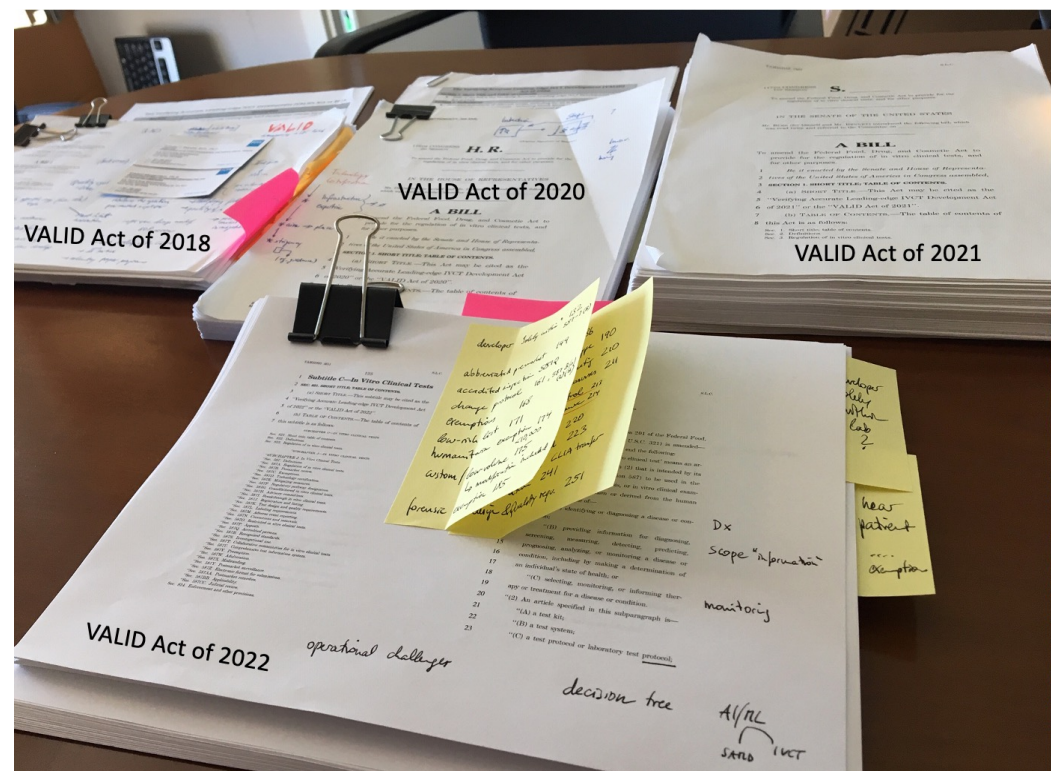


Food and Drug Administration Safety and Landmark Advancements Act (FDASLA)



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 —



298

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

9 **SEC. 587T. COLLABORATIVE COMMUNITIES FOR IN VITRO**
 10 **CLINICAL TESTS.**

11 **“(a) IN GENERAL.—”**

12 **“(1)** For the purposes of facilitating community
 13 solutions and decision making with respect to in
 14 vitro clinical tests, the Secretary may participate in
 15 collaborative communities comprised of public and
 16 private participants that may provide recommendations
 17 and other advice to the Secretary on the development
 18 and regulation of in vitro clinical tests.

19 **“(2)** A collaborative community under this
 20 section shall have broad representation of interested
 21 private and public-sector stakeholder communities
 22 and may include patients, care partners, academics,
 23 health care professionals, health care systems,
 24 payors, Federal and State agencies, entities responsible
 25 for accrediting clinical laboratories, inter-

CPT Codes AMA Digitization of slides



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	<ul style="list-style-type: none"> ● X018T ● X019T ● X020T ● X021T ● X022T ● X023T ● X024T ● X025T ● X026T ● X027T ● X028T ● X029T ● X030T 	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	<ul style="list-style-type: none"> ● X044T ● X045T 	Establish codes X044T, X045T, X046T, X047T to report artificial intelligence (AI) to ECG data for possible detection and autonomous generation



Truthing & Validation

Updates
from
Truthing &
Validation
WG



CENTER FOR DRUG EVALUATION AND RESEARCH

What's New in Regulatory Science

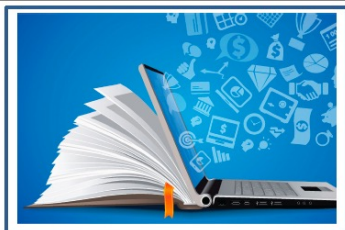


Issue I - 2022

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 *in 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 checkpoint 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

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

Table of Contents

I.	INTRODUCTION.....	1
II.	BACKGROUND.....	2
III.	DEVELOPMENT OF CTDNA AS A BIOMARKER FOR REGULATORY USE IN EARLY-STAGE SOLID TUMOR CLINICAL TRIALS	2
	A. ctDNA for Patient Selection based on Molecular Alteration:.....	2
	B. ctDNA Molecular Residual Disease for Patient Enrichment:	3
	C. ctDNA as a Measure of Response.....	4
IV.	ASSAY CONSIDERATIONS.....	5
	A. Types of Molecular Residual Disease Panels.....	5
	B. Sampling Considerations	5
	C. Assay analytical validation considerations for marketing applications.....	6
V.	INVESTIGATIONAL DEVICE CONSIDERATIONS.....	7

Proposal:
Cell Free
Working
Group



Update: APPIA officially joined Plcc



Collaboration on a protocol development project is in the works

PathML
Presentation
June 6, 10AM ET

PATHML

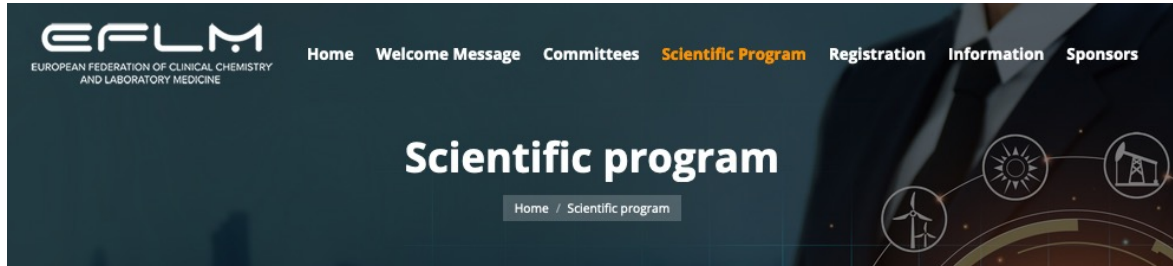
An open-source software
toolkit for computational
pathology research

Presented by Renato Umeton, PhD &
Jacob Rosenthal, MSc

Monday, June 6, 2022
10:00-11:00 AM Eastern Time



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 emerging 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

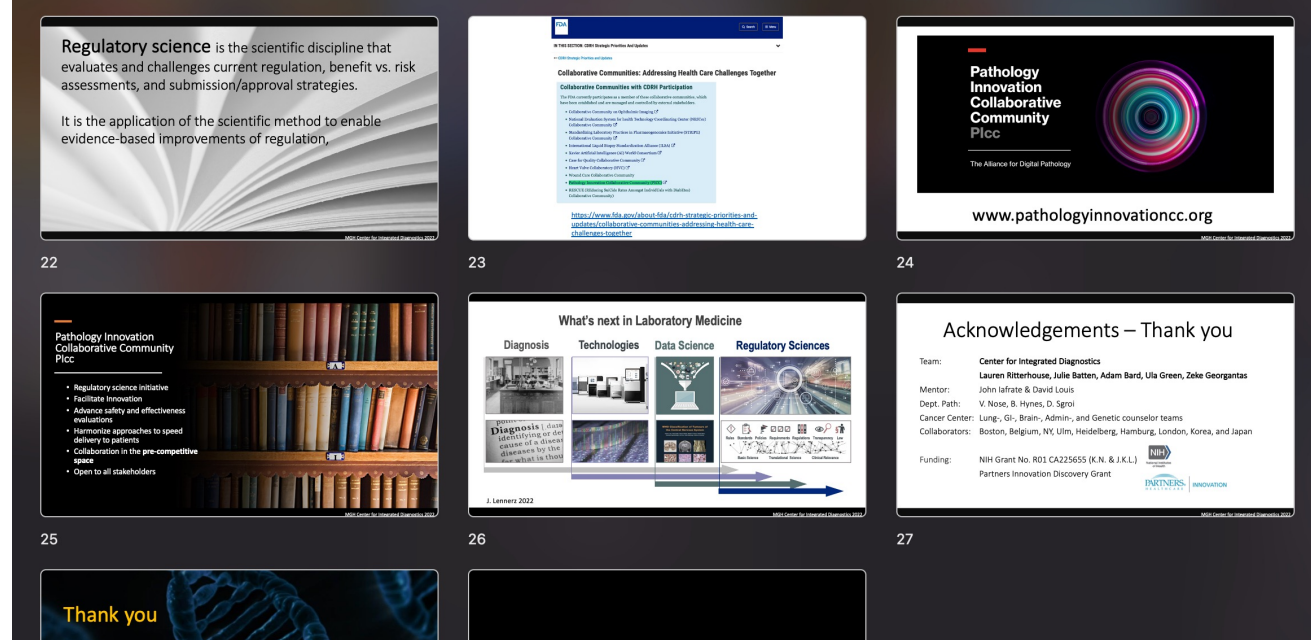
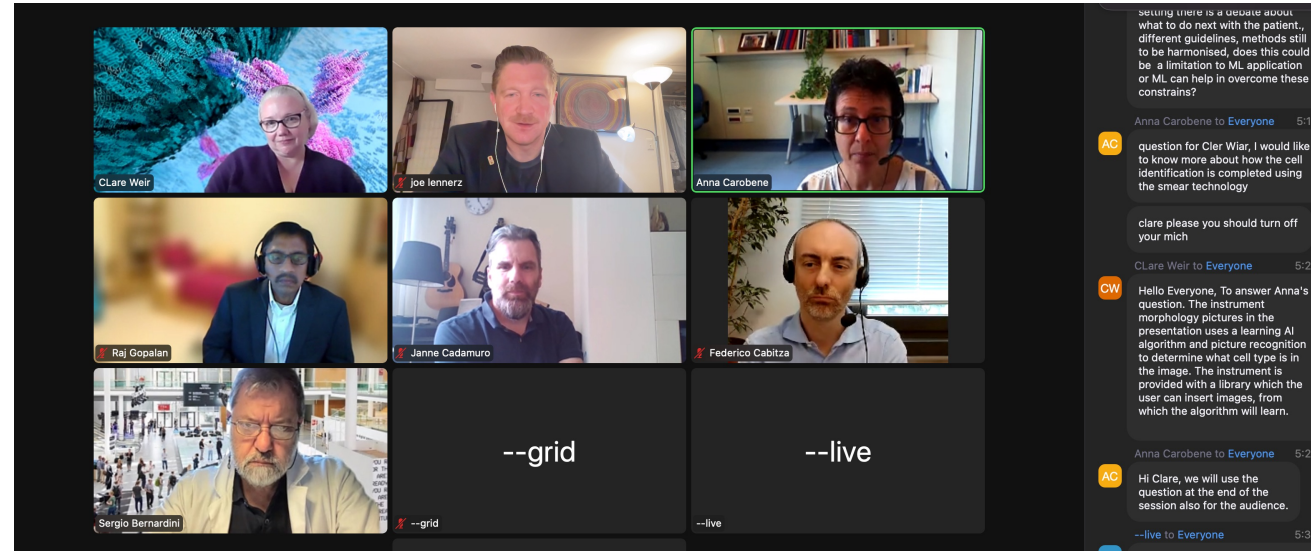
Raj Gopalan (Siemens Healthineers Diagnostics, Chief Medical Information Officer and Global Head of Clinical Decision Support)

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

• The Importance of Regulation of AI/ML in the Laboratory

Jochen K. Lennerz (Medical Director, Center for Integrated Diagnostics, Harvard Medical School)

• Discussion



June 3-7, 2022 • McCormick Place • Chicago, IL &
Online

#ASCO22

Abstract Titles Released

Preview the 2,800+ abstracts covering 120+ abstract subcategories spanning all major disease sites and research areas that will be presented at the meeting.

Digital Pathology & AI Congress: USA

WHEN
14th-15th Jun 2022

WHERE
New York, USA
Long Island Marriott

READ THE AGENDA

REGISTER ONLINE

THE LENS OF INNOVATION

OCTOBER 16-18 | MGM GRAND | LAS VEGAS, NV

#PathVisions22



ICDP 2022: 16. International Conference on Digital Pathology
November 14-15, 2022 in Paris, France



ECDP 2022 18th EUROPEAN CONGRESS ON DIGITAL PATHOLOGY
REGISTER NOW
15th-18th of June 2022 | Berlin, Germany
www.ecdp2022.org
ESDIP EUROPEAN SOCIETY OF DIGITAL AND INTELLIGENT PATHOLOGY

Events of interest

Next Steering Committee: Wednesday, June 29 3PM ET



**Pathology
Innovation
Collaborative
Community
Plcc**

The Alliance for Digital Pathology

