



**Pathology
Innovation
Collaborative
Community
Plcc**



Steering Committee Meeting
October 27, 2021

DPA Pathology Visions 2021 Recap

2021 PATHOLOGY
VISIONS

SAVE THE DATE

OCTOBER 17-19 | MGM GRAND | LAS VEGAS, NV



DICOM WG-26 WSI Annotation Hackathon

A virtual [Hackathon](#) for collaborative development and testing of software for the generation, exchange, and use of whole slide image (WSI) annotations in DICOM SEG, ANN, or SR format, in which anyone (vendors, academics, and individuals) can participate freely and openly.

Venue

The event will be held virtually over the internet from Monday, September 27, 2021 to Friday, October 15, 2021. Interoperability demonstrations will be conducted between Monday, October 11, 2021 and Friday, October 15, 2021 (exact dates and times will be scheduled with participants via email after registration). A working prototype should be available by Monday, October 11, 2021 to allow for interoperability demonstrations to start on time. A final summary session and panel discussion will take place live at the [Pathology Visions 2021](#) conference in Las Vegas on Tuesday, October 19, 2021 9:45-10:30 AM PDT.

Collaborative Communities FDA Townhall

 The Alliance for Digital Pathology FDA Camera	 Joe Lennerz	 Mimi Nguyen	 Michelle Tarver	Vickie Driver
Ben Brown	Ariana Albiar	 Mark Blumenkranz	Michael Mack	Martin Leon
Yiduo.Wu@fda.hhs.gov	Katharine Barnard-Kelly	Jennifer Goldsack (DATAcc / ...)	 Jithesh Veetil (MDIC)	 Marla Phillips (Xavier University)
 Joe Sapiente	 Dana Connors	 Sandra Siami (MDIC/NESTcc)	 Francisco.Vicenty@fda.hhs.gov	 Zivana.Tezak@fda.hhs.gov
 Matthew.Diamond@fda.hhs.gov	 Malvina.Eydelman@fda.hhs.gov	 Brandon.Gallas@fda.hhs.gov	 Cynthia.Chang@fda.hhs.gov	Nada Hanafi

1/2

Harvard-MIT Center for Regulatory Science

Global Conference on Regulatory Science 2021

October 12-13, 2021 | Virtual Conference

KEYNOTE



Bakul Patel

Director, Digital Health Center of Excellence, US FDA

SPEAKERS

Christian Johner, Johner Institute

Ariel Stern, Harvard Business School

John Torous, Beth Israel Deaconess Medical Center

Charmaine Demanuele, Pfizer

Ralph Brindis, ACC National Cardiovascular Data Registry

Robert "Joe" Mather, Pfizer

Craig Lipset, Decentralized Trials & Research Alliance

Yvonne Chan, Digital Medicine Society

Anindita Saha, Digital Health Center of Excellence, FDA

Henrik Matthies, German Federal Ministry of Health

Steven Vandeput, mHealthBelgium

Anna Essen, Swedish Center for Digital Innovation

Derk Arts, Castor

Leonard Sacks, Office of Medical Policy, CDER, FDA

Florence Bourgeois, Boston Children's Hospital

Scott Steele, University of Rochester Medical Center

Andy Coravos, HumanFirst

Peter Sorger, Harvard-MIT Center for Regulatory Science

Sandro Santagata, Brigham and Women's Hospital

VIDEOS

Document open for public comment:

Machine Learning-enabled Medical Devices - A subset of Artificial Intelligence-enabled Medical Devices: Key Terms and Definitions from International Medical Device Regulators Forum (IMDRF)

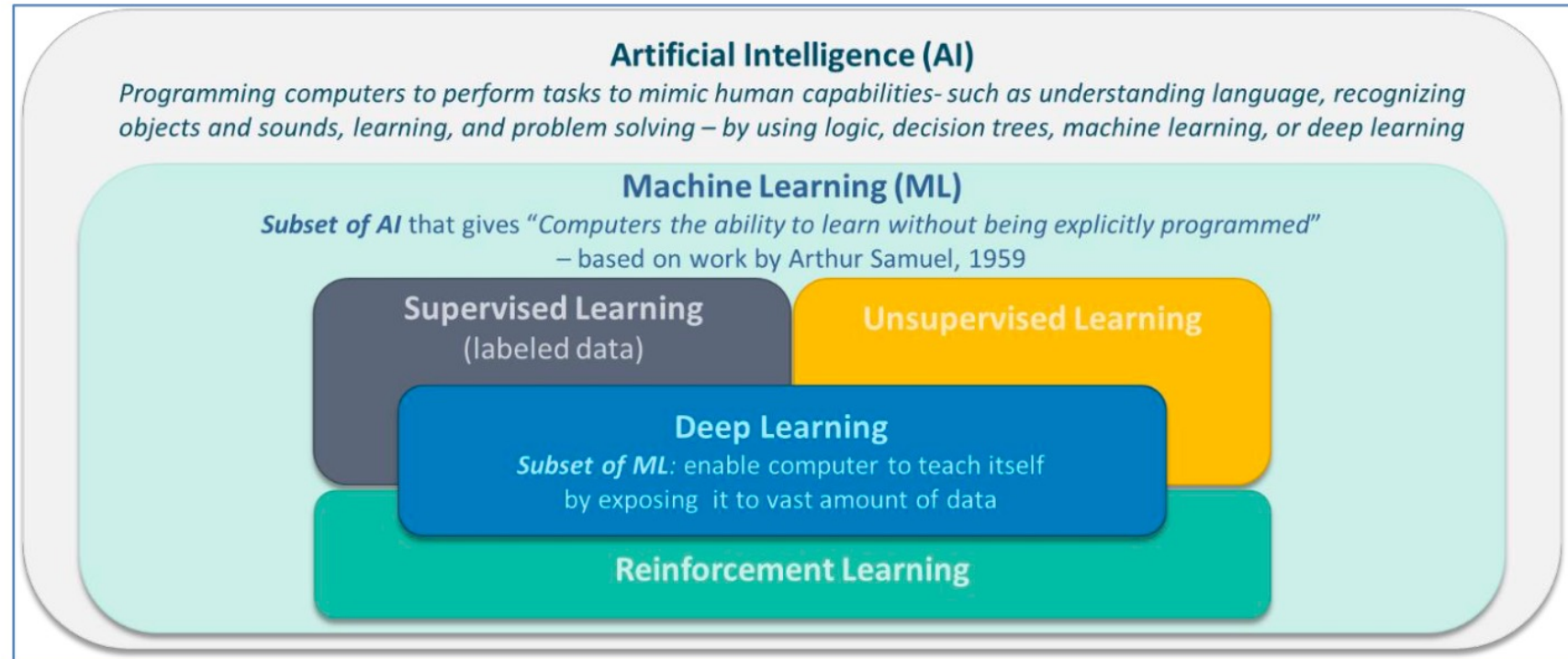


Figure 1 Overview of AI and ML Concepts

Good Machine Learning Practice for Medical Device Development: Guiding Principles

The U.S. FDA, Health Canada, and the United Kingdom's MHRA have jointly identified 10 guiding principles that can inform the development of Good Machine Learning Practice (GMLP).

Good Machine Learning Practice for Medical Device Development: Guiding Principles	
Multi-Disciplinary Expertise Is Leveraged Throughout the Total Product Life Cycle	Good Software Engineering and Security Practices Are Implemented
Clinical Study Participants and Data Sets Are Representative of the Intended Patient Population	Training Data Sets Are Independent of Test Sets
Selected Reference Datasets Are Based Upon Best Available Methods	Model Design Is Tailored to the Available Data and Reflects the Intended Use of the Device
Focus Is Placed on the Performance of the Human-AI Team	Testing Demonstrates Device Performance During Clinically Relevant Conditions
Users Are Provided Clear, Essential Information	Deployed Models Are Monitored for Performance and Re-training Risks are Managed

Job Announcements

- **26 October 2021:** DIDSR Deputy Director
 - [Job posting on LinkedIn](#)

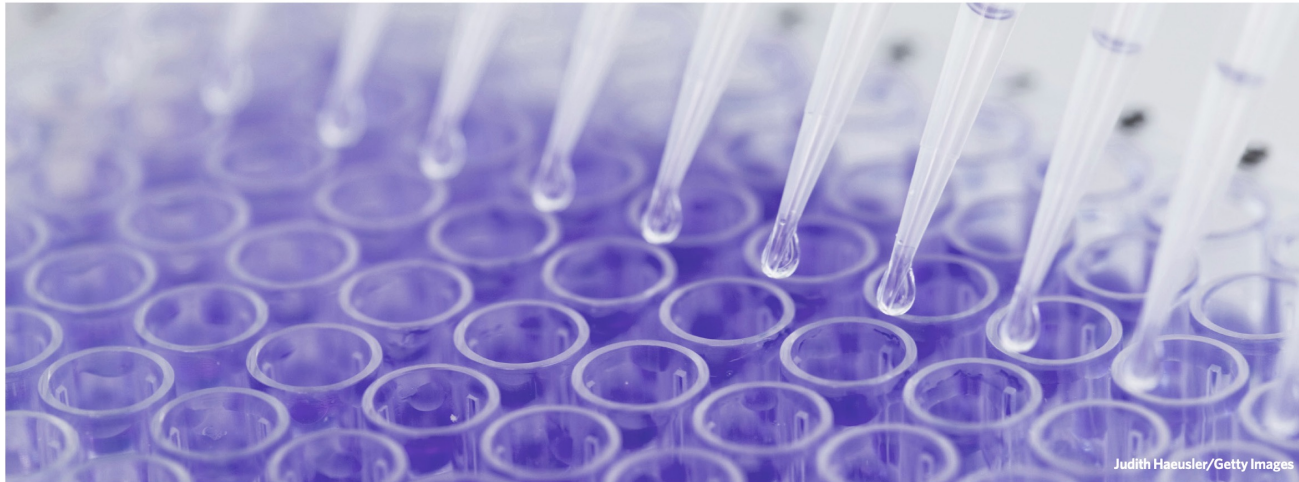
- **15 October 2021:** Job Opportunities in OSEL (Office of Science and Engineering Labs)
 - [Job posting](#)
 - This link should be persistent and updated

PEW Charitable Trusts

Fact Sheet



Oct 2021



Diagnostic Tests Not Reviewed by FDA Present Growing Risks to Patients

Congress should pass reforms to ensure accuracy, reliability, and quality



The Role of Lab-Developed Tests in the In Vitro Diagnostics Market

As lab-developed tests grow increasingly complicated, federal oversight has lagged

REPORT October 22, 2021 Topics: [Health Care & U.S. Policy](#) Projects: [Health Care Products](#)

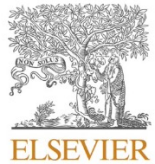
The Role of Lab-Developed Tests in the In Vitro Diagnostics Market

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The potential of AI in cancer care and research



Contents lists available at [ScienceDirect](https://www.sciencedirect.com)

BBA - Reviews on Cancer

journal homepage: www.elsevier.com/locate/bbacan



The potential of AI in cancer care and research

Norman E. Sharpless, M.D. ^{*}, Anthony R. Kerlavage, Ph.D.

National Cancer Institute, Bethesda, MD, United States of America

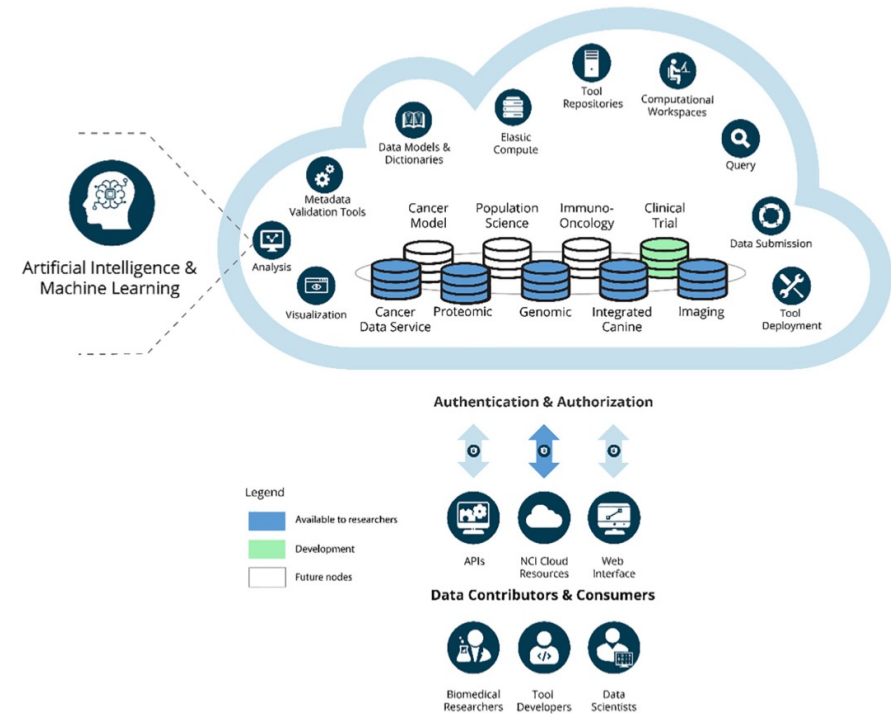
ARTICLE INFO

Keywords:
Artificial intelligence
Machine learning

ABSTRACT

Current applications of artificial intelligence (AI), machine learning, and deep learning in cancer research and clinical care are highly diverse—from aiding radiologists in reading medical images to predicting oncoprotein folding and dynamics. The list of available AI-based tools is growing rapidly and will only continue to expand. With the immense potential for AI to advance cancer research and clinical care, the National Cancer Institute (NCI) has a responsibility to consider and support the development and evaluation of such technologies. NCI's current involvement in AI research spans the spectrum of development, implementation, and assessment. That includes generating large, publicly available, curated datasets; shifting the culture of data sharing; training the next generation of scientists in both AI and cancer sciences; fostering interdisciplinary collaborations; investing in research to improve AI methods and models that are designed specifically for cancer; widening access to computing power; procuring computer architecture for future developments; and assuring AI research and technologies follow ethical principles. In addition to a broad overview of AI applications in cancer research and care, and NCI's ongoing AI-based activities, this Perspective outlines NCI's four priority areas for future investment of cancer-focused AI development.

NCI's Cancer Research Data Commons includes a cloud-based analytics infrastructure that provides user workspaces for AI/ML analysis and development.



Trainee WG Speaker Event

Siba el Hussein

November 22
9AM ET



Upcoming Plcc Meetings



Test Driving VALID2021
Thursday, October 28 3-4PM ET

Privacy Pilot Project P



Privacy Pilot Project
Friday, October 29 12-1PM ET

Payor Strategies



Payor WG Meeting
Tuesday, November 2 1-2PM ET

MDIC Update

- Discussion: define "membership" for Plcc

Upcoming Events

- **November 4:** Collaborative Community Senior Leadership Team Meet [internal]
- **November 8-9:** Artificial Intelligence in Oncology Symposium: Precision Medicine and Cancer Disparities

1 Pathology Innovation Collaborative Community "Pie CC" SLT Update

2 Pathology Innovation Collaborative Community Overview of Public Health Issue

- Cancer is diagnosed using the microscope
- Pathology is the ground truth for many applications, but data is missing from the electronic medical record
- The workflow remains analog
- Technology and innovation around digital pathology, pre-clinical, and the market is \$30 annually
- The evidence framework for digital pathology and AI/ML is still lacking
- The central vision of the collaborative community is to work in an inclusive community for all stakeholders regarding pre-competitive regulatory science activities related to pathology innovation

Membership: 514 Members + 31 meetings

Regulators or Government	18%
Professional Organizations	2%
Academia or Clinical	20%
Industry	60%

3 Goals of Pathology Innovation CC

- Historically, the various stakeholders either professors and/or clinicians are leading the pursuit of using technology and innovation
- Our goal is to facilitate pathology innovation in the pre-competitive space through applied regulatory science
- Establish an inclusive platform for stakeholders

4 Pathology Innovation CC at Work

Mission: Full membership meeting (March), Identify steering committee members, 2 web-based speakers/events, 2 workshop meetings, 3 peer-reviewed publications (concept, training, peer-reviewed), ALL MATERIALS AVAILABLE ONLINE

5 FDA guidance documents related to digital pathology

6 Working Groups, Projects, Presentations

