Health Advances™

AI in Diagnostics – Where Are We Really?

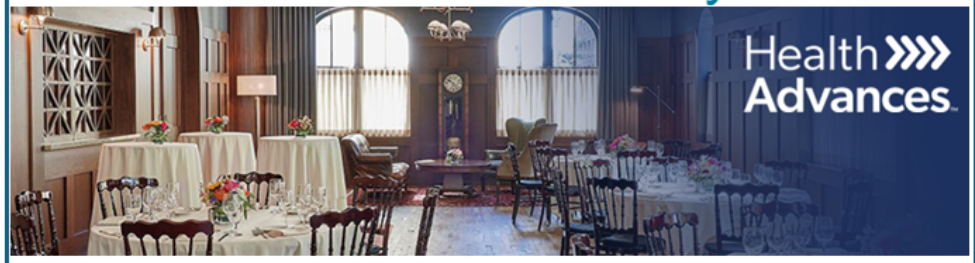
Health Advances ADLM Panel Summary

August 2024

Health Advances 2024 ADLM panel, *"AI in Diagnostics - Where are We Really?"* debated the current status, challenges and opportunities for using AI in clinical diagnostics.

Health Advances invites you to our
15th Annual ADLM Cocktail Reception and Panel

AI in Diagnostics: Where are We Really?



Date: Tuesday, July 30, 2024
Time: Cocktails @ 5:30pm CST, AI Panel @ 6:30pm CST
Location: The Chicago Firehouse Restaurant 1401 S Michigan Ave, Chicago, IL 60605

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The term "AI" (artificial intelligence) is used on every website and echoes through conference halls, boardrooms, and coffee shops. But what lies beyond the buzz? AI's true impact on diagnostics remains a subject of both fascination and skepticism. From assisting in test and assay development, to analyzing complex data sets and constructing predictive models, to being part of the test itself providing new clinical information, to clinician decision support tools, to providing labs with advanced operational support, AI holds much promise, but we are not there yet. In this panel, we will dive into the promises, pitfalls, and practical applications of AI in diagnostics. Discussion will consider technical, clinical, business model, and regulatory factors. Bring your questions and join Health Advances for an enlightening conversation.

Moderators

- **Peter Origenes**, *Vice President*, Health Advances
- **Chris Karras**, *Vice President*, Health Advances

Panelists

- **Tim Sweeney**, *CEO*, Inflammatix
- **Paul Beresford**, *Vice President and General Manager CDx*, Agilent Technologies
- **James A. Boiani,** *Partner,* Epstein, Becker, and Green

How do we define AI in diagnostics and what opportunities exist?

What is the current state of AI in diagnostics today?

What challenges must be addressed for AI to maximize its impact in Dx?

What are the key next steps for AI in Dx?

Panelists

James A. Boiani, MS, JD

Shareholder, Epstein Becker & Green, P.C.

- James A. Boiani is a Shareholder in the law firm of Epstein Becker Green. James has extensive experience with FDA regulation of pharmaceuticals, medical devices, *in vitro* diagnostics and lab developed tests, helping innovators develop premarket strategies, prepare FDA submissions, and navigate postmarket compliance & commercialization matters.
- James helps client navigate the FDA regulatory landscape regarding of AI/ML in diagnostics, clinical decision support software, digital therapeutics, and products used in supporting pharmaceutical and biotech industries. James also advises investors in the life sciences on a wide range of regulatory matters that affect valuation and business planning.

Tim Kuruvilla

SVP, Global Head of Commercialization, Roche Information Solutions

- Tim Kuruvilla is the Global Head of Go-To-Market Roche Information Solutions (the company's digital health business)
- Prior to Roche, Tim was Co-founder and Chief Commercial Officer at Viewics (acquired by Roche in 2017). Viewics was the market leader in laboratory clinical and operational analytics, with prominent customers such as Mayo Clinic and partnerships with 3 of the 4 largest diagnostics companies.
- Prior to Viewics, Tim was a founding member of the Applied Technology Investing Team at Opus Capital.
- He began his career at Stockamp & Associates (acquired by Huron), a leader in revenue cycle and patient progression projects with premier medical centers and health systems across the U.S.

Tim Sweeney, MD, PhD

Cofounder and CEO, Inflammatix, Inc.

- Tim Sweeney is the co-founder and CEO of Inflammatix. While training at Stanford he helped invent Inflammatix's core technology and is named on over a dozen patents related to medical diagnostics.
- Tim's clinical and scientific experience span general surgery & critical care medicine, bench research, bioinformatics and machine learning.
- He has published over 100 manuscripts & abstracts and holds positons on the editorial boards of *Critical Care Medicine* and *Diagnostics*.
- Through Inflammatix he is the Principal Investigator on multiple development contracts from DARPA, BARDA, and the NIH. He sits on the steering committee of the Sepsis Alliance Infection Management FDA Collaborative Group.

Moderators

Peter Origenes

Vice President, Health Advances

- Peter joined Health Advances in 2019 bringing over 30 years of healthcare experience including corporate executive, principal investor and strategy consulting positions across diagnostics and life sciences products.
- Prior to joining Health Advances, Peter held executive positions at Becton Dickinson, GE Healthcare and Ortho Clinical Diagnostics. Previously, was a Partner with Radius Ventures, a consultant with The Wilkerson Group and Bain. His early career includes tenure with Schering-Plough, Genentech and Roche Laboratories.
- Peter holds a Master of Science in Industrial Administration from the Tepper School at Carnegie Mellon University, and bachelors' degrees in Genetics and History from the University of California at Berkeley.

Chris Karras

Vice President, Health Advances

- Over the past 25 years, Chris has worked closely with leading companies across the diagnostics and biopharma industries on a broad array of issues.
- Prior to joining Health Advances, Chris served as a Director in Global Strategic Marketing in the Rapid Diagnostics Division of Abbott.
- Previously, Chris spent 15 years in management consulting, primarily with Arthur D. Little's Healthcare and Strategy Practices. He served as a Director in Strategy Development at Pharmacia and as an Equity Analyst at Prudential. Chris began his career at Abbott in Core Lab Diagnostics (ADD) and Corporate Finance.
- Chris holds a BBA degree from the University of Iowa and an MBA from the Booth School of Business at the University of Chicago.

How do we define AI in diagnostics and what opportunities exist?

Defining AI in Diagnostics

Artificial intelligence is a tool for large scale ***pattern recognition,*** capable of leveraging ***numerous and varied biomarkers and other data*** to better diagnose and manage patient health, as well as support laboratory clinical and administrative operations

Application Categories

- Supporting Dx development including signature identification, “engineering” the test to meet priority needs for clinical decisions
- Stratifying at-risk and diagnosed patients across a wide array of disease areas
- Enhancing clinical workflow and accuracy using digital image management and interpretation (for slide based tests)
- Expansion of data capture in patient/clinician interactions and interpreting details to support clinical decisions for “right test, right patient, right time”
- Capture of valuable data for medical management beyond the clinical setting
- Improving lab operations and instrument reliability
- Optimizing billing, coding, revenue cycle management and other administrative functions

“The opportunities for AI are still being discovered and things that seem impossible today will be commonplace in 5-10 years ”

“AI is evolving to become the diagnostic tool itself, taking numerous inputs and creating a generalizable output for a specific condition or clinical question”

“With more content across larger populations, we will have greater capability in risk assessment across ESRD, sepsis and other conditions”

“AI promises greater efficiency and workflow across clinical, lab and administrative processes”

Source: Health Advances ADLM AI in Dx panel..

What is the current state of AI in diagnostics today?

Data Infrastructure, Collection and Analysis

- *"A huge amount is being spent in creating data infrastructure. The risk that potential will not be realized is much lower than the potential to realize way larger value from these investments"*
- *"Its too early to say AI has transformed diagnostics but not too early to say it will be transformational"*
- *"The ability capture all of the information from a patient clinician interaction is now present, passively"*
- *"The home environment is now accessible as a source of data to be captured and used productivity, so we are pushing our digital pathology products to be able to address this shortage."*

AI in Dx is already present, Improving Lab Operations, collecting information and communicating with patients…

- *"We are collecting millions of datapoints from all our instruments ,AI helps us be proactive on where problems might occur so we can address before there there is an actual issue."*
- *"We are leveraging AI quite extensively in software development. Engineers don't need to be as highly trained in a specific capability and we can supplement with AI to get them started and progress from there."*
- *"Patient context, communications, interactions and directions for diagnostic/care pathways can be orchestrated after acute events or een proactively"*

Clinical Applications Are Emerging

Digital Pathology

"We have a shortage of pathologists. We need to optimize their productivity, so we are pushing our digital pathology products to be able to address this shortage, improving efficiency and accuracy"

Sepsis

"AI sepsis algorithms are rapidly emerging with recent FDA approval. There is high unmet need and the variety of possible relevant markers examined plays into the strength of AI."

Cancer Risk and Outcomes

"In a wide range of cancer LDTs, we have progressed from disease signatures to algorithmic predictions of future risk and probable treatment outcomes, employing large adjudicated data sets"

Source: Health Advances ADLM AI in Dx panel..

What challenges must be addressed for AI to maximize its impact in Dx?

Ensuring high quality data remains a challenge

- *"At a foundational level, the data is still too messy and time consuming to clean up. We need to address how we can integrate disparate data and structure it so it is high quality and useful for the models in development."*

Clinical Performance Must Improve and Become More Generalizable

- *"These tests are being developed in small patient populations at a single site. As soon as tools leave the first test site, they stop working. We need large enough training datasets that accurately represent the entire relevant population."*
- *"Creating something that is better than the background is really difficult, so we better have a good idea of what the clinical action will be and who will be responsible for doing it"*

Regulatory Pathways Need to Operate at Speed of Innovation

- *"We need a framework for validity of markers that can be consistently applied"*
- *"The FDA enacted pre-determined change controls in 2022, but it is not being sufficiently leveraged for IVD products. These will be crucial for broader implementation of AI in diagnostics.*
- *"The best AI based tests will continue to learn and evolve as real world use delivers more and better data .This will lead to a need for modifications along the way to realize the value of the evolution. If each small change results in a six-month FDA review, we will lose out on one of the key benefits of AI."*

Create Alignment on Ethical Implications

- *"Creating ethical principles and navigating risk management will be key, particularly around what are our obligations for testing. If an algorithm evolves and has 5% better accuracy, are we required to retest everyone and share the results? We need to determine what level of liability all stakeholders will have."*
- *"Algorithms will improve as we use these tools in clinical practice, we have the moral responsibility to improve the tests, educate and implement"*

Source: Health Advances ADLM AI in Dx panel..

What are the key next steps for AI in Dx?

Continue Infrastructure and Data Standardization to Better Access and Compare Data

- *"It is essential to build the infrastructure capabilities so we have a high degree of rigor around the data foundations and how to structure data"*
- *"We need a customer focused effort on infrastructure so we can demonstrate and improve capabilities."*

Improve Stakeholder Trust and Education on the Benefits and Caveats of AI Today

- *"Being transparent about the process is essential…clinicians' concern is in being able to trust a test went through the same rigorous evaluation as any other diagnostic they use today."*
- *"The truth is there will be bias in these models. We need to convince people that even with that bias, it is better than what they have today and will continue to improve with more time and data."*

Ethical Standards Norms are Required across Stakeholders

- *"We operate in scientific organizations and we need the principles to build the right way and get our organizations to a better place in using the power of AI"*
- *"Creating ethical principles and navigating risk management will be key, particularly around what are our obligations for testing and re-testing"*

Source: Health Advances ADLM AI in Dx panel..

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