MDIC
Medical Device
Innovation Consortium

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# MDIC Updates

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# ModSim and MXR 2024 Recap!



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## ENABLING DIGITAL PATHOLOGY WITH ARTIFICIAL INTELLIGENCE

**1:40 Chairperson's Remarks**

*Jithesh Veetil, PhD, Senior Program Director, Digital Health & Technology, Medical Device Innovation Consortium*

**1:45 Advancing the AI in Diagnostics and Healthcare: Role of the Public-Private Partnership Model**

*Jithesh Veetil, PhD, Senior Program Director, Digital Health & Technology, Medical Device Innovation Consortium*

Novel technologies including AI promise to revolutionize healthcare, from earlier diagnosis to better treatments and improved clinical care. Some of the perpetual concerns are the scarcity of data and the uncertainty in the regulatory frameworks. In addition, many of the stakeholders in the fast-moving space are working in silos. This presentation will highlight a few concrete examples of how public-private partnerships such as MDIC are bringing together stakeholders.

**2:15 PANEL DISCUSSION: Unlocking the Potential of Digital Pathology and Artificial Intelligence (AI) through Regulatory Science**

*Moderator: Jithesh Veetil, PhD, Senior Program Director, Digital Health & Technology, Medical Device Innovation Consortium*

Industry and regulatory leaders will discuss advances in digital pathology and AI as well as progress and hurdles in the quest to broadly implement digital pathology and AI/machine learning. The impact of recent regulatory and legislative developments in digital pathology and AI tools in diagnostics will be highlighted as well as the work of the Pathology Innovation Collaborative Community, a regulatory science initiative that aims to facilitate innovations in pathology.

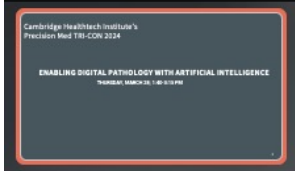
*Panelists:*

*Maryellen de Mars, PhD, Program Director, Clinical Diagnostics, Medical Device Innovation Consortium*

*Jochen Lennerz, MD, PhD, Director, Center for Integrated Diagnostics, Massachusetts General Hospital; Associate Professor, Pathology, Harvard Medical School*

*Keith Wharton, Jr, MD, PhD, Global Medical Affairs Leader - Pathology, Roche Diagnostics Solutions*

**3:15 Close of Conference**



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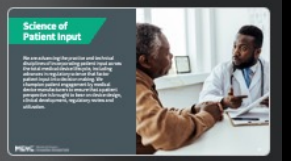

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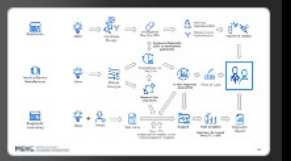
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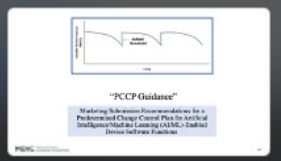

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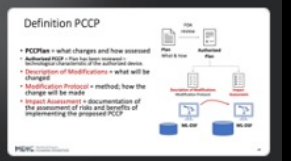

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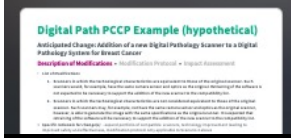


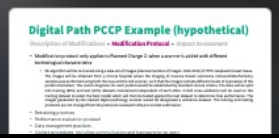


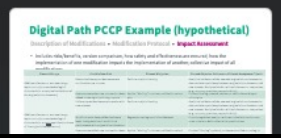

Presenter View

# Ongoing Projects

## Digital Health Technology

| Digital Health (Software Vertical) | Medical Extended Reality (MXR) | Cybersecurity | Computational Modeling & Simulation (CM&S) | Pathology Innovation Collaborative Community (PIcc) |
|---|---|---|---|---|
| 1a: WG on PCCP & Quick Reference Guide<br>1b: WG on Software Design Considerations<br>1c: WG on Post-market Software Change Considerations<br>4: WG on Software Submission Best Practices<br>**Pipeline**<br>1. Health at Home/Bring Your Own Device/Health Technology (BYOD/H)<br><br>**Co-chairs of Steering Committee:**<br>Matthew Walker (FDA/DHCoE)<br>Cassie Scherer (Medtronic) | 1. WG on Human Factors<br>2. WG on Image Quality<br>3. WG on Training & Education<br>4. WG on Taxonomy<br>4. WG on MXR2024 Summit<br><br>**Co-chairs of Steering Committee:**<br>Ryan Beams (FDA/OSEL)<br>Heather Benz (J&J) | 1. WG on PenTest Best Practices<br>2. WG on Industry Maturity Benchmarking & Annual Report<br>3. Threat Modeling Bootcamps<br><br>**Co-chairs of Steering Committee:**<br>Aftin Ross (FDA/OSTP)<br>Chris Reed (Medtronic) | 1. WG on Public Funded Human Models<br>2. WG on Blood Damage Modeling<br>3. WG on CM&S2024 Symposium<br><br>**Co-chairs of Steering Committee:**<br>Ed Margerrison(FDA/OSEL)<br>Vacant | Multiple community working groups on digital pathology with monthly community meeting<br><br>**Co-chairs of Steering Committee:**<br>Brandon Gallus (FDA/OSEL)<br>Joe Lennerz (MGH/Harvard) |

MDIC Medical Device Innovation Consortium

**MDIC Staff**
**Program Director**
Jithesh Veetil
**Project Managers**
Taylor Montgomery (Software Vertical & CM&S)
Noor Falah (Cybersecurity & PIcc)
Jennifer Waters (MXR)

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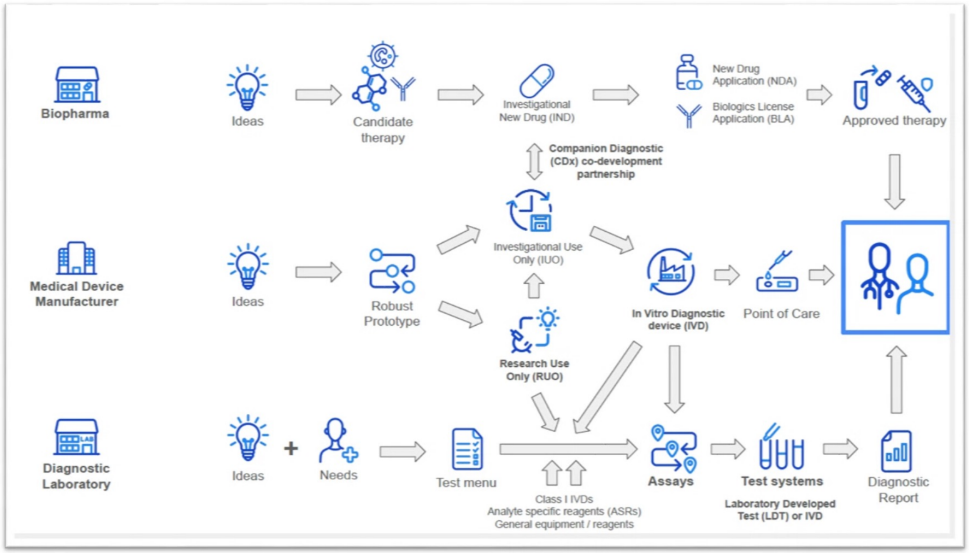
410 Show Laptop

# Critical & nonoveralpping roles of pharma, MDMs, and Dx laboratories in medical care




MDIC Medical Device Innovation Consortium

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# Europe and Beyond



Federal Office
for Information Security

# Generative AI Models

Opportunities and Risks for Industry and Authorities

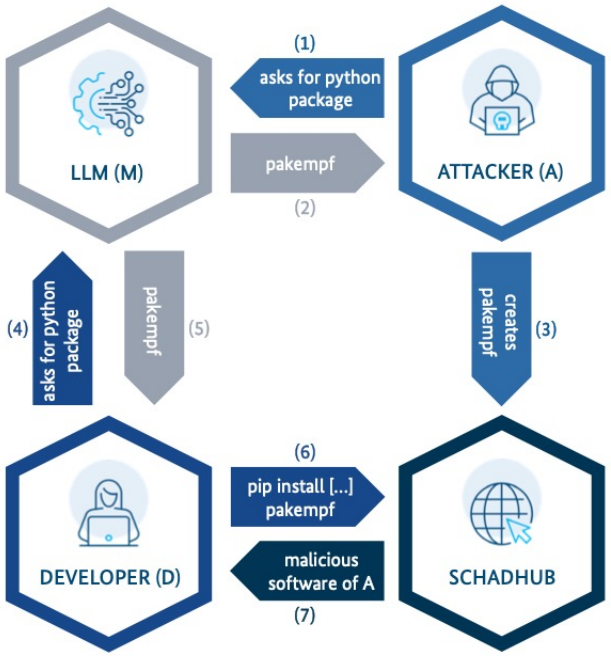



*Figure 1: Flowchart for misuse of hallucinated package names*

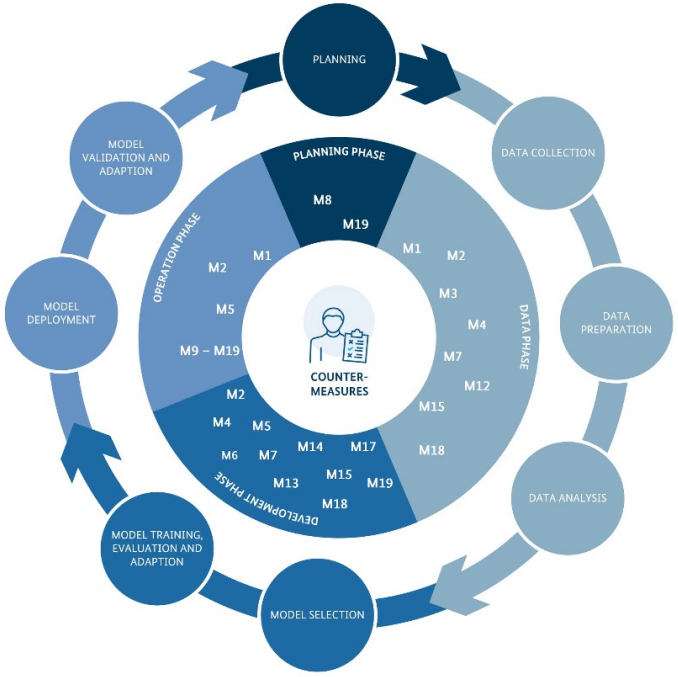



*Figure 3: Countermeasures in the lifecycle of an LLM*

# Environnement digital et santé des populations

MATHIEU JENDLY[a], Pre VALÉRIE SANTSCHI[b], Pr VIKTOR VON WYL[c,d] et Pr ARNAUD CHIOLERO[a,e,f]

*Rev Med Suisse 2024; 20: 808-12 | DOI: 10.53738/REVMED.2024.20.870.808*

**La santé et le risque de maladies sont déterminés par l'exposition aux environnements physiques, socio-économiques et politiques, et à cela s'est ajouté l'exposition à l'environnement digital. Notre vie digitale a des implications majeures, d'une part, sur la santé des populations et son monitoring et, d'autre part, sur la prévention et les soins. Ainsi, la santé digitale (digital health), qui englobe l'utilisation d'applications de santé, d'appareils connectés, ou d'outils médicaux d'intelligence artificielle, modifie les pratiques médico-soignantes. Bien utilisée, elle pourrait faciliter les soins centrés sur le patient, interprofessionnels et guidés par les données. Cependant, sa mise en œuvre soulève d'importants craintes et enjeux éthiques en lien notamment avec la protection des données, l'équité et la relation thérapeutique.**

les soins (figure 1). Elle soulève les questions de littératie numérique, de protection des données, d'éthique ou d'équité dans l'accès aux services de santé fournis digitalement.[1]

Élément émergeant de cet environnement digital, la santé digitale (eHealth) est un vaste champ englobant des catégories telles que la santé mobile (mHealth), les dispositifs portables, ou la télémédecine. Elle tire profit de la digitalisation croissante de notre quotidien, via notamment la miniaturisation des senseurs ouvrant la voie à des collectes de données en continu et en temps réel,[2] et les développements de l'intelligence artificielle (IA). Elle change – et pourrait améliorer – les pratiques de prévention et de gestion des maladies.

L'objectif dans cet article est d'examiner certaines implica-

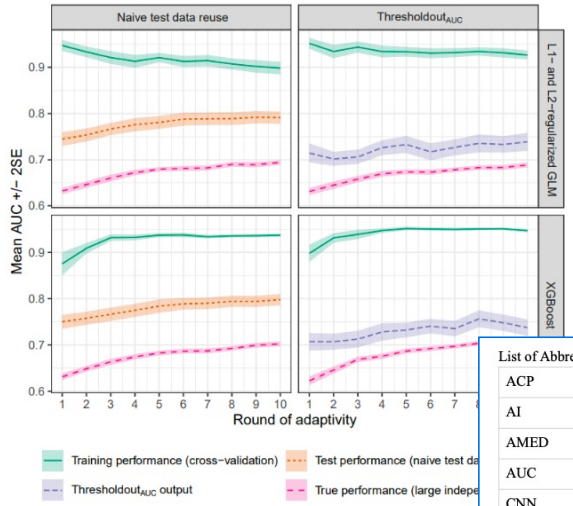
Provisional Translation*

# Report on AI-based Software as a Medical Device (SaMD)

**August 28, 2023**

**Subcommittee on Software as a Medical Device Utilizing AI and Machine Learning of the Science Board**

* This English translation of the document submitted to PMDA by the Science Board is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail. The PMDA will not be responsible for any consequence resulting from the use of this English version.




List of Abbreviation

| | |
|---|---|
| ACP | Algorithm Change Protocol |
| AI | Artificial Intelligence |
| AMED | Japan Agency for Medical Research and Development |
| AUC | Area Under the Curve |
| CNN | Convolution Neural Network |
| DL | Deep Learning |
| DICOM | Digital Imaging and Communications in Medicine |
| FDA | U.S. Food and Drug Administration |
| GMLP | Good Machine Learning Practice |
| IDATEN | Improvement Design within Approval for Timely Evaluation Notice |
| IEC | International Electrotechnical Commission |
| IID | independent and identically distributed |
| IMDRF | International Medical Device Regulations Forum |
| ISO | International Organization for Standardization |
| ML | Machine Learning |
| MLMD | Machine Learning-enabled Medical Device |
| PEMS | Programmable Electric Medical Systems |
| PMDA | Pharmaceuticals and Medical Devices Agency |
| SaMD | Software as a Medical Device |
| SPS | SaMD Pre-Specifications |
| WSI | Whole-Slide Imaging |

# Professional Societies

# Reimbursement Impact of the FDA Regulations

**FDA Budget Impact for Preparation & Submission of Labs in addition to the cost of registering a lab with the FDA, which in 2023 was about $6,493*:**

**PMA- High Risk Assays-** Ranges from $10's thousand to $100's thousand to prepare and up to **$500K to submit***

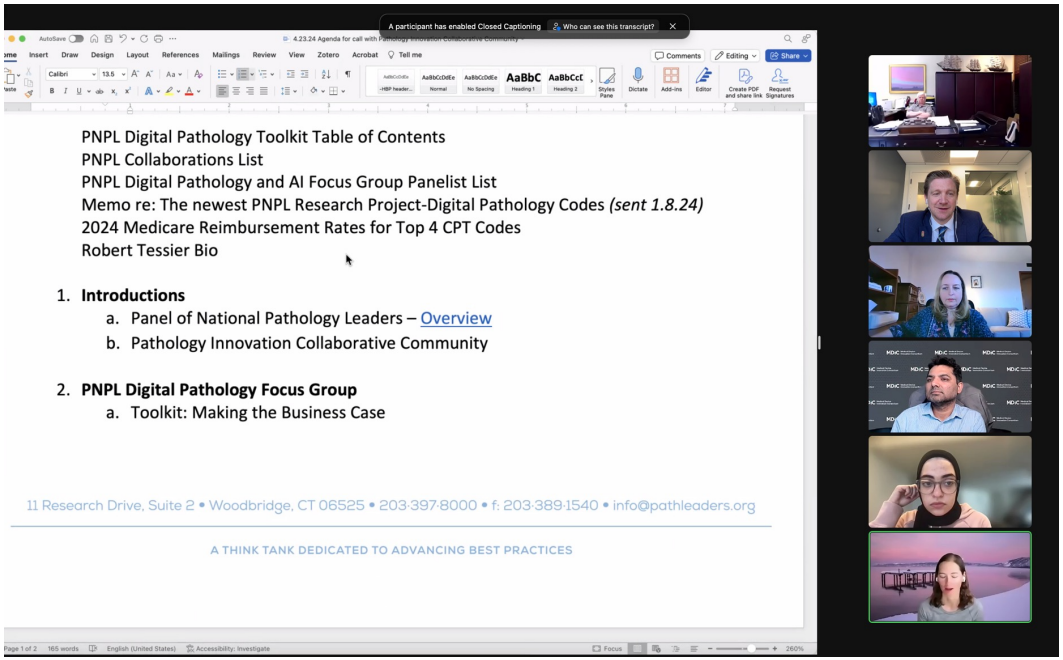
**De Novo- Moderate Risk:** Ranges from $10's thousand to $100's thousand to prepare and up to **$150K to submit***

**510K- Low to Moderate Risk:** Ranges from $10's thousand to $100's thousand to prepare and around **$20K to submit***

*The De Novo request provides a marketing pathway to classify novel medical devices for which general controls alone, or general and special controls, provide reasonable assurance of safety and effectiveness for the intended use, but for which there is no legally marketed predicate device.

**Sarah Clancey Overton**
Revenue Cycle Management

Velsera




PNPL
PANEL OF NATIONAL PATHOLOGY LEADERS

# What's New in Pathologist Productivity and Compensation

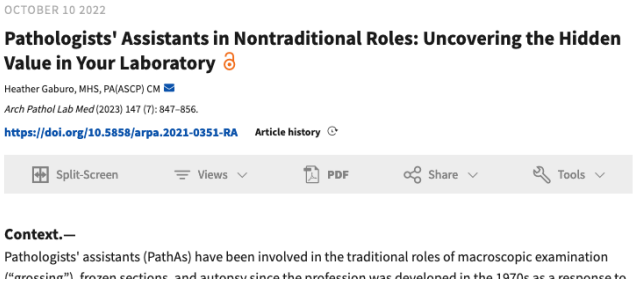
## Plus Boosting Profitability through Effective Negotiations with Hospitals and Payers

Executive War College ◦ Tuesday, April 30, 2024

11 Research Drive, Suite 2 • Woodbridge, CT 06525
203·397·8000 • info@pathleaders.org

**Heather Gaburo, MHS, PA(ASCP)CM**
***Technical Director, Panel of National Pathology Leaders***

**Allegra Klein**
***Executive Director PNPL***


OCTOBER 10 2022

**Pathologists' Assistants in Nontraditional Roles: Uncovering the Hidden Value in Your Laboratory**

Heather Gaburo, MHS, PA(ASCP) CM

*Arch Pathol Lab Med* (2023) 147 (7): 847–856.

https://doi.org/10.5858/arpa.2021-0351-RA Article history

Split-Screen Views PDF Share Tools

**Context.—**

Pathologists' assistants (PathAs) have been involved in the traditional roles of macroscopic examination ("grossing"), frozen sections, and autopsy since the profession was developed in the 1970s as a response to

**Robert Tessier, MPH**
Panelist & Co-Founder
*Panel of National Pathology Leaders*

After receiving his Master's in Public Health from UNC Chapel Hill, Bob Tessier consulted for community and academic radiology groups, including practice plans and third-party negotiations. In 1982, Cornell/NY Hospital retained him to establish the first fee-for-service pathology practice in NYC. He later did the same for Yale Pathology and has since negotiated over 300 third-party contracts. In 2019, Bob founded the *Panel of National Pathology Leaders*, a "think tank" advancing innovation in pathology and laboratory medicine. PNPL includes 400 pathologists, Digital Pathology, Diagnostic Medicine, and Corporate Social Responsibility research groups, and multiple networking teams.

Contact: rtessier@pathleaders.org


APRIL 5, 2024 • NEW YORK, NY
Digital Pathology Course
Includes an optional guided tour of Memorial Sloan Kettering's pathology laboratory areas (space limited).


30TH ANNIVERSARY
AMP2024
ANNUAL MEETING & EXPO
NOVEMBER 19-23, 2024
VANCOUVER
BRITISH COLUMBIA, CANADA


ECDP2024
20th EUROPEAN CONGRESS ON DIGITAL PATHOLOGY
ESDIP
ecdp2024.org
5th · 8th June 2024
Vilnius, Lithuania
SAVE THE DATE


Save the date
36th European Congress of Pathology
7 – 11 September 2024
Fortezza da Basso, Florence, Italy
European Society of Pathology


REGISTER NOW
PV24
PATHOLOGY VISIONS24
DECISION DIGITAL
ADVANCING DIGITAL PATHOLOGY TOGETHER
DPA
NOVEMBER 3-5, 2024 • ORLANDO, FL • HYATT REGENCY

# PIcc DPA Visions Meeting – Proposal 1 of 2

**Title:** ***Advancing Regulatory Science in Digital and Computational Pathology: A Collaborative Dialogue***

**Abstract:** In an era of rapid technological advancements, the integration of digital and computational pathology into clinical practice has become increasingly prevalent. The Pathology Innovation Collaborative Community (PIcc), convened by the Medical Device Innovation Consortium (MDIC), recognizes the critical importance of regulatory science in this evolving landscape. As such, we propose a dedicated session at the 2024 Visions meeting to foster collaborative dialogue on regulatory topics within digital and computational pathology.

# PIcc DPA Visions Meeting – Proposal 2 of 2

**Session Objectives:**

1. Provide an overview of current regulatory advances and challenges in digital and computational pathology.
2. Highlight the role of collaborative communities, such as PIcc, in advancing regulatory science and fostering industry-academia-regulatory partnerships.
3. Share perspectives and insights from regulatory agencies, including the Center for Devices and Radiological Health (CDRH)/FDA, on regulatory considerations for digital pathology technologies.
4. Facilitate a panel discussion featuring representatives from PIcc, MDIC, regulatory agencies, and industry to explore diverse viewpoints on regulatory topics and identify opportunities for collaboration.

**Session Format:** ?

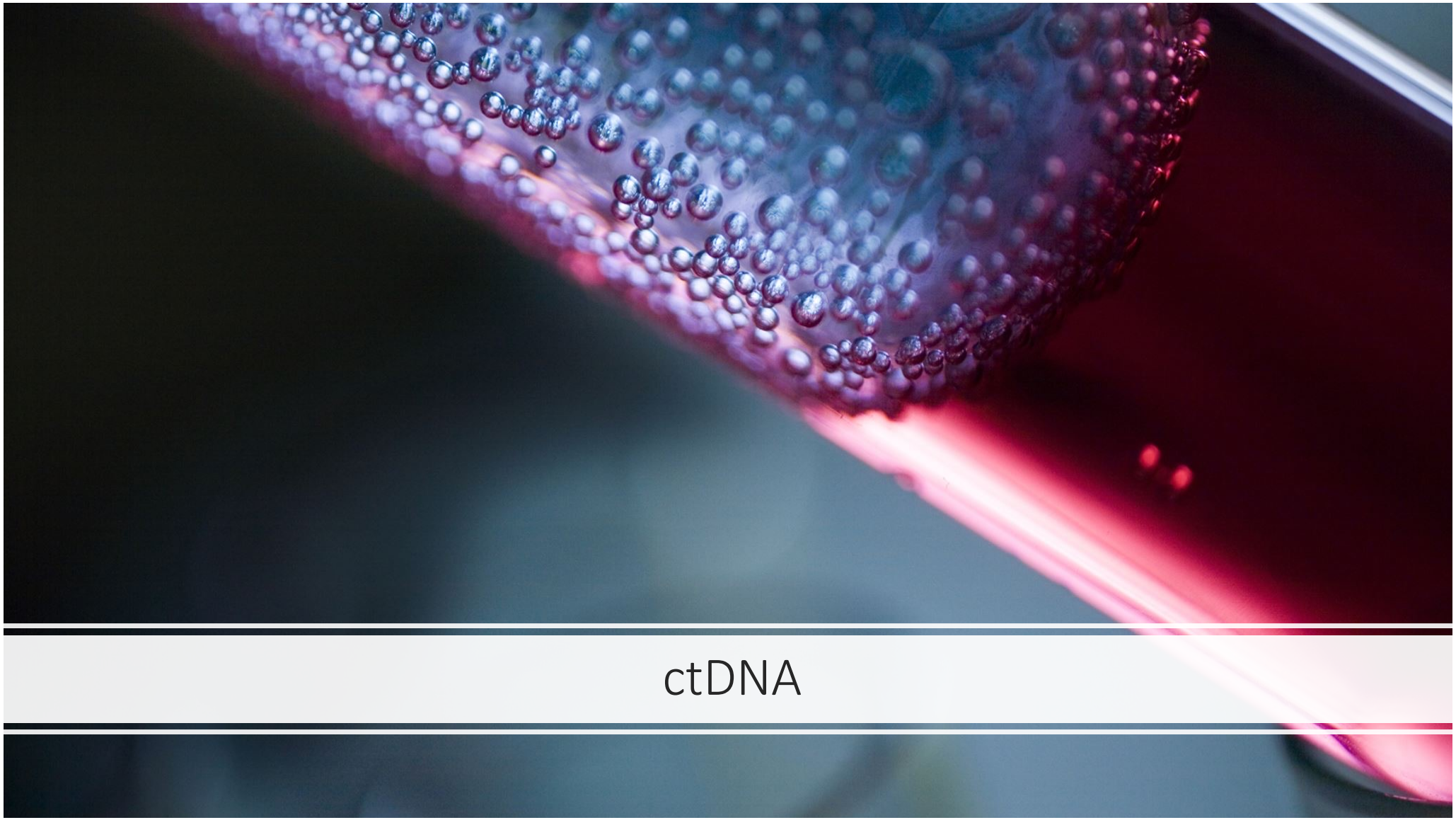
The session will consist of selected talks by representatives from PIcc, MDIC, regulatory agencies (e.g., FDA), and relevant stakeholders, followed by a panel discussion moderated by experienced leaders in regulatory science. Talks will address specific regulatory challenges, innovative approaches, and collaborative initiatives in digital and computational pathology.

The panel discussion will provide an opportunity for interactive engagement and exchange of ideas among participants.

# Plcc DPA Visions Meeting – Discussion

- Pre-conference workshop $7,500 or
- Submission as proposal for oral presentation

- Preference
- …



# ctDNA

# New Frontiers in Liquid Biopsies: Data, Technology and Translational Potential

May 13 - 14, 2024



## General Information

For conference-related questions please contact

**NCI Frederick Conference Planners**

conferenceplanning@mail.nih.gov
301.228.4027

## Location

**National Institutes of Health**

Building 45
45 Center Drive
Bethesda, MD 20892

ADD TO CALENDAR

## Overview


Building on the foundation of cell-free DNA prenatal testing, the field of liquid biopsy research has rapidly evolved, with uses spanning from early detection of cancer and monitoring of organ transplants. Unlike traditional biopsy methods that require invasive procedures to obtain tissue samples, liquid biopsies use simpler methods to detect disease markers, including cells themselves, in different biofluids, including blood, urine, and even cerebral spinal fluid. This less invasive approach allows for repeated monitoring over time.

Attending the conference will be an excellent opportunity to stay up-to-date on the latest developments and advancements in the field of liquid biopsies. Researchers and professionals from all over the world will be sharing their insights and results, and you'll have the chance to network with others in the field, providing valuable opportunities for collaboration, learning, and professional growth. Young investigators and trainees are especially encouraged to attend career roundtable discussions over lunch, and all attendees are invited to submit abstracts for poster sessions on both days of the conference as well as for consideration for short oral presentations. In keeping with NIH's mission to provide equitable and inclusive conference experiences, attendance is free -- there will be no registration fee for any attendees. This conference is open to members of the NIH community, academic researchers outside of the NIH, and members of pharma/industry.

**Registration is due by Friday, April 26th.**

## Registration

REGISTER NOW!

nature medicine

Article

https://doi.org/10.1038/s41591-024-02877-z

# Neoadjuvant nivolumab or nivolumab plus LAG-3 inhibitor relatlimab in resectable esophageal/gastroesophageal junction cancer: a phase Ib trial and ctDNA analyses

Received: 5 June 2023

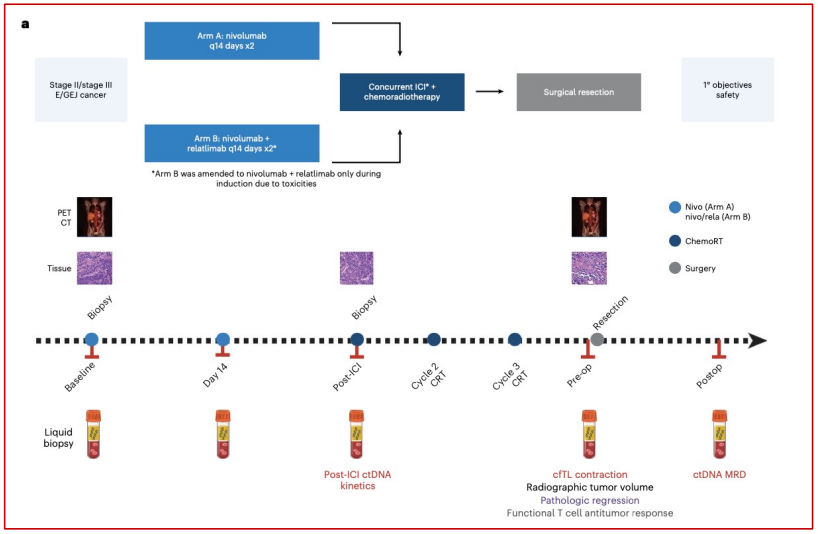
Accepted: 16 February 2024

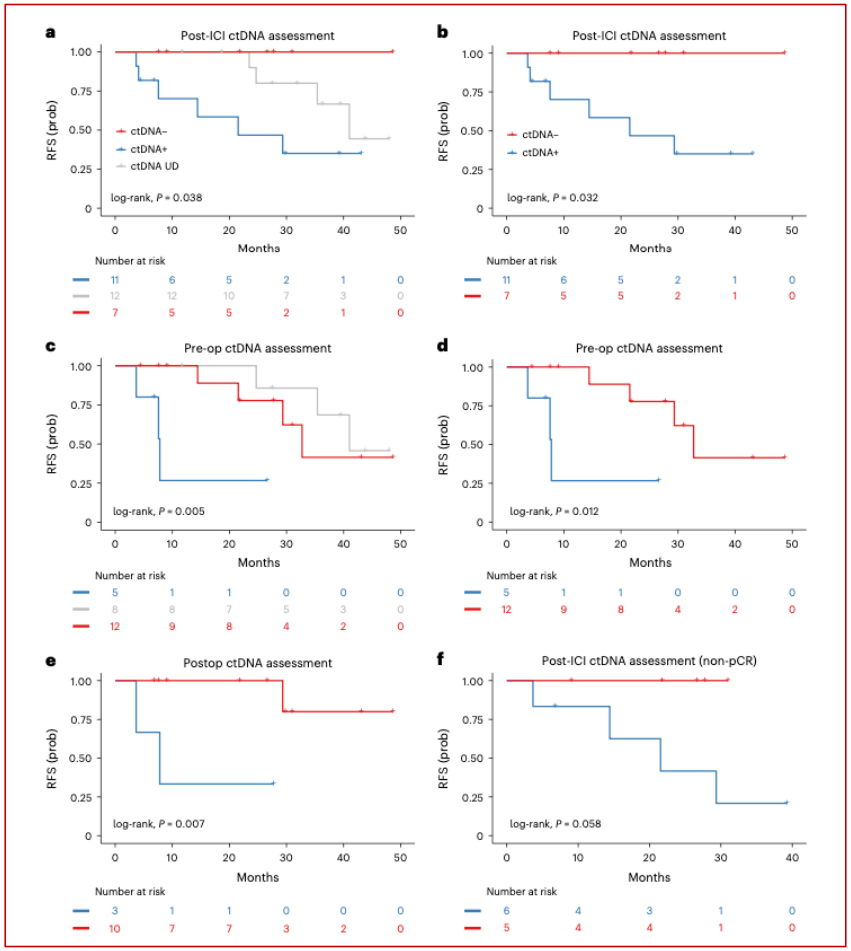
A list of authors and their affiliations appears at the end of the paper

Gastroesophageal cancer dynamics and drivers of clinical responses

Ronan J. Kelly[1,11], Blair V. Landon[2,11], Ali H. Zaidi[3,11], Dipika Singh[2,4], Jenna V. Canzoniero[2], Archana Balan[2], Russell K. Hales[2,5], K. Ranh Voong[2,5], Richard J. Battafarano[6], Blair A. Jobe[3], Stephen C. Yang[6], Stephen Broderick[6], Jinny Ha[6], Kristen A. Marrone[2,4], Gavin Pereira[7], Nisha Rao[2], Aryan Borole[2], Katerina Karaindrou[2], Zineb Belcaid[2], James R. White[2], Suqi Ke[2,7], Ali I. Amjad[3], Benny Weksler[3], Eun Ji Shin[8], Elizabeth Thompson[9], Kellie N. Smith[2,4], Drew M. Pardoll[2,4], Chen Hu[2,7], Josephine L. Feliciano[2], Valsamo Anagnostou[2,4,10,12] & Vincent K. Lam[2,12]

[1]The Charles A. Sammons Cancer Center, Baylor University Medical Center, Dallas, TX, USA. [2]The Sidney Kimmel Comprehensive Cancer Center, Johns




Exploratory analyses of circulating tumor DNA (ctDNA) showed that patients with undetectable ctDNA post-ICI induction, preoperatively and postoperatively had a significantly longer RFS and OS

# Diversity Equity & Inclusion

MERVE HICKOK AND EVANNA HU

# Don’t Let Governments Buy AI Systems That Ignore Human Rights

Even in the absence of broader AI regulation, federal procurement provisions could set expectations for data quality, model performance, risk assessments, and documentation.

# Patient advocacy

Cytotherapy 000 (2024) 1–7

Contents lists available at ScienceDirect

CYTOTHERAPY

journal homepage: www.isct-cytotherapy.org

Full-Length Article

# Accelerating the development of genetically engineered cellular therapies: a framework for extrapolating data across related products

Mark D. Stewart[1,*], Michael Kalos[2], Vicki Coutinho[3], Marc Better[4], Jonathan Jazayeri[5], Jennifer Yohrling[6], Julie Jadlowsky[7], Miriam Fuchs[8], Shalini Gidwani[9], Carsten Goessl[10], Patrick J. Hanley[11], Jane Healy[12], Wen Liu[13], Brittany A. McKelvey[1], Laura Pearce[14], Shari Pilon-Thomas[15], Hillary S. Andrews[1], Monica Veldman[16], Judy Vong[17], Susan P. Weinbach[18], Jeff D. Allen[1]

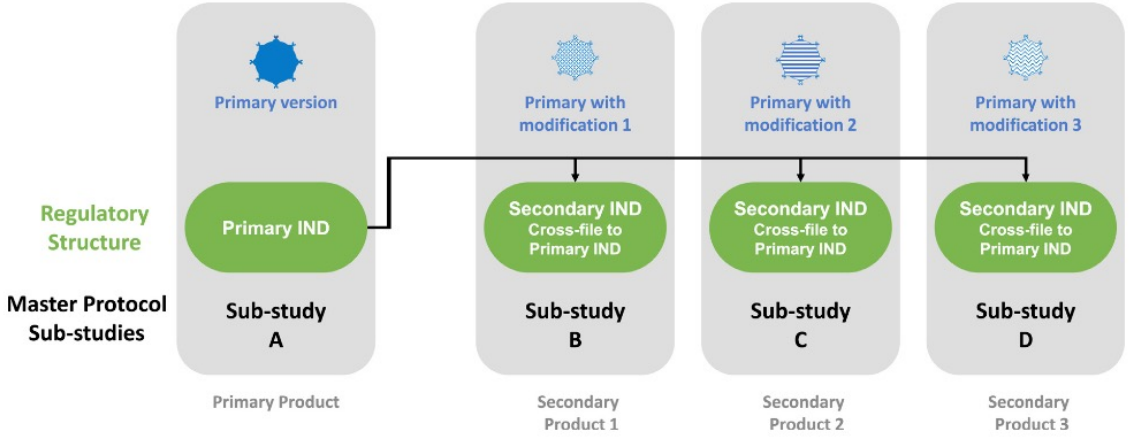



**Fig. 1.** Umbrella trial design for primary and secondary products. The proposed umbrella trial can simultaneously evaluate multiple product versions for a specific disease or condition using a single-trial infrastructure, design, and master protocol, allowing for more efficient product development.

# Resources

# Building consistency in HER2 IHC assessment

## The pathologists behind HER2Know

Educational materials developed with the Pathology Faculty.

**Marilyn Bui**
MD, PhD
Senior Member and Professor in the Department of Pathology, Moffitt Cancer Center & Research Institute
View profile ›

**Michael Feldman**
MD, PhD
Chair of the Department of Pathology and Laboratory Medicine, Indiana University School of Medicine
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**David Hicks**
MD
Professor and Director of IHC-ISH Laboratory and Breast Subspecialty Service, University of Rochester Medical Center
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**Shabnam Jaffer**
MD
Chair of the Department of Pathology and Laboratory Medicine, Lenox Hill Hospital, Northwell Health and Professor, Hofstra Northwell School of Medicine
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**Thaer Khoury**
MD
Vice Chair of Anatomic Pathology and Chief of Breast Pathology, Roswell Park Comprehensive Cancer Center
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**Savitri Krishnamurthy**
MD
Professor of Pathology, The University of Texas MD Anderson Cancer Center
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**Gary Tozbikian**
MD
Associate Professor and Breast Pathology Division Director, The Ohio State University Wexner Medical Center
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**Shi Wei**
MD, PhD
Professor of Pathology and Laboratory Medicine, The Barbara F. Atkinson Endowed Professor, Director of Translational Research, University of Kansas Medical Center
View profile ›

**Hannah Wen**
MD, PhD
Director, Breast Pathology Fellowship, Memorial Sloan Kettering Cancer Center
View profile ›

HER2, human epidermal growth factor receptor; IHC, immunohistochemistry; ISH, in situ hybridization.

Washington and Lee Law Review Online

Volume 81 | Issue 4 Article 1

3-26-2024

# The Wild, Wild West of Laboratory Developed Tests

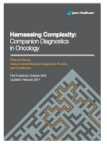
John Gilmore
*Washington and Lee University School of Law*, gilmore.j24@law.wlu.edu

# MASTERING COMPLEXITY:

## The path towards a cancer-free reality

**PIETER DE RICHTER**
The Ipsos Global Oncology Centre of Expertise
November 2023

### A journey through complexity




**Harnessing Complexity**
2017 (updated from 2015)


**Conquering Complexity**
2017

As this is the final paper in a series of three, let us wrap up with a look back at the journey of discovery that started with Harnessing Complexity, way back in 2015 (with a later update in 2017). We began by highlighting that the treatment of cancer has become significantly more complex since the arrival of companion diagnostics, and that the relationship between those diagnostics and their clinical utility is not always a straightforward one.

We reviewed perceptual data taken from the Ipsos Molecular Diagnostics (MDx) Monitor, which showed that a majority of HCPs agreed with the clinical utility of testing for key biomarkers, despite a lack of universal consensus. We discussed the relative benefits and drawbacks of drugs being approved for all patients versus a specific patient subject whose tumours harbour specific mutations or overexpression profiles. We delved deeper into different methodologies for testing, and the use of different test kits, and looked at real-world behaviour data from the Ipsos MDx Monitor to showcase that there is a high degree of fragmentation when it comes to the uptake of those methodologies and kits.

Towards the end of the first paper, we briefly cast our minds to the (then) future, bringing up the concepts of Next Generation Sequencing and liquid biopsies as having the potential to revolutionise the companion diagnostics landscape. We concluded by stating that cancer is complex, and that an understanding of its complexity leads to opportunities that can be harnessed by doctors, and by drug and diagnostics manufacturers, ultimately benefiting the patient.

In Conquering Complexity, first written in 2017 and then updated in 2022, we dove much deeper into the ongoing revolution, analysing both the NGS market and the liquid biopsy market in greater detail. Again, we drew upon data from the Ipsos MDx Monitor to highlight the perceptions and actual behaviour of healthcare professionals to illustrate the profound impact those twin revolutions were – and still are – having on the oncology treatment landscape. We then looked at the intersection of those two trends, bringing up the concept of liquid-biopsy based NGS panels.


**Conquering Complexity**
(updated) 2022


**Mastering Complexity**
2023

Wrapping up the second paper, we once again looked towards the future, introducing many of the concepts that this third and final paper focuses on in greater detail. We noted in the 2022 update that we were only in the early stages of an accelerating revolution in molecular diagnostics; even one year later, this feels like an understatement.

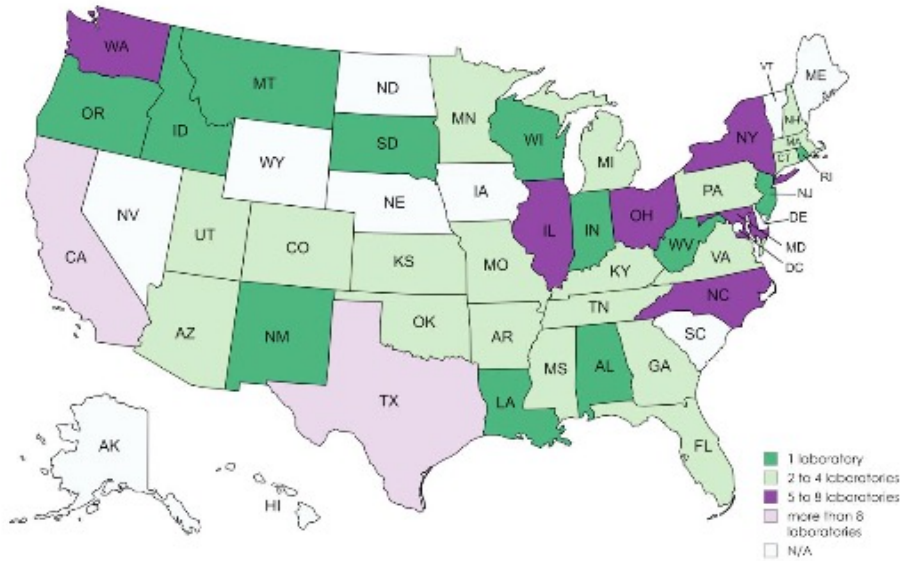
That brings us to this third and final paper, in which the distant future takes centre-stage, and in which we explore highly theoretical concepts that may one day allow us to achieve the goal stated in the title. If the world of AI-powered nanobots and mind uploading seems very far removed from the opening paragraphs of the first paper, this is by design. The concept of testing a tumour sample for common DNA mutations and then choosing a targeted therapy based on this information, as straightforward and entrenched as it may now seem, is in itself an incredible achievement that was simply inconceivable in the era of non-targeted chemotherapies. Human ingenuity and perseverance in the face of this truly insidious enemy has given us a number of remarkable tools to hit cancer at the most fundamental level. While the battle is far from over, who really knows what the future holds?

In closing, this third and final paper is dedicated to hope: to the hope for a future in which we no longer have to deal with resistance mutations, no longer have to regularly subject patients to frequent biopsies, no longer have to painstakingly try to come up with a drug sequencing plan for patients with rare combinations of mutations, no longer have to tell patients that unfortunately there are no more viable options to treat their cancer. To the hope that this future will come fast enough for the many cancer patients who are out there whose oncologists are desperately trying to find a path through the layers of complexity.

To the hope that, one day, life without cancer will be a simple reality.

ADLM Association for Diagnostics & Laboratory Medicine™
Formerly AACC

**ADLM Member Feedback: Assessing Responses to FDA's Proposed LDT Regulation Survey**




**Results and Interpretations**

**Number of responding laboratories:**
140 US-based laboratories


# Generative AI for the Public Sector: The Journey to Scale

**MARCH 26, 2024**

By Miguel Carrasco, Cyma Habib, Frank Felden, Richard Sargeant, Steven Mills, Simon Shenton, Jamie Ingra and Gareth Dando

## Exhibit 4 - Government Partnerships for Working with GenAI

| | 1 Universities and training providers | 2 Technology companies | 3 Industry | 4 External advisors |
|---|---|---|---|---|
| Experiment and learn | • Targeted funding to accelerate GenAI R&D<br>• Access specialized knowledge<br>• Workforce upskilling | • Access technology expertise<br>• Help establish sandboxed environment to encourage experimentation | • Provide early guidance on safe use of GenAI<br>• Establish GenAI research and innovation hubs | • Identify priority use cases<br>• Conduct GenAI maturity assessments<br>• Prototype and build pilots |
| Refine, scale, and optimize | • Integrate the use of GenAI into university courses to upskill the future workforce<br>• Conduct research on the social implications of GenAI | • Transition to new technology to enable GenAI<br>• Long-term contracts and GenAI panel agreements<br>• Embed RAI principles in products | • Regulate the use of GenAI<br>• Facilitate data-sharing partnerships between government departments and industry | • Design, build, deploy, and scale use cases<br>• Implement new operating model and processes<br>• Upskill talent and coach on the job |

# Concerns for pediatric care related to device regulation

## Laboratory Developed Tests Regulation Survey

The Association for Diagnostics & Laboratory Medicine (ADLM) is concerned that the Food and Drug Administration (FDA) proposed rule to regulate laboratory developed tests (LDTs), in addition to current regulation under the Centers for Medicare and Medicaid Services (CMS), would hinder the ability of hospitals and academic centers to deliver timely diagnoses and care to patients.

To gauge the impact on patient care, ADLM recently conducted the first of several surveys that focused on hospital laboratories, with special attention to those that specialize in pediatric care. The responses underscored that FDA regulation of LDTs would impose new burdens that would directly affect care. In particular, many children's hospitals stated they would be forced to outsource tests to commercial labs or switch to alternative FDA-approved tests, both of which could delay and impair diagnosis and treatment.

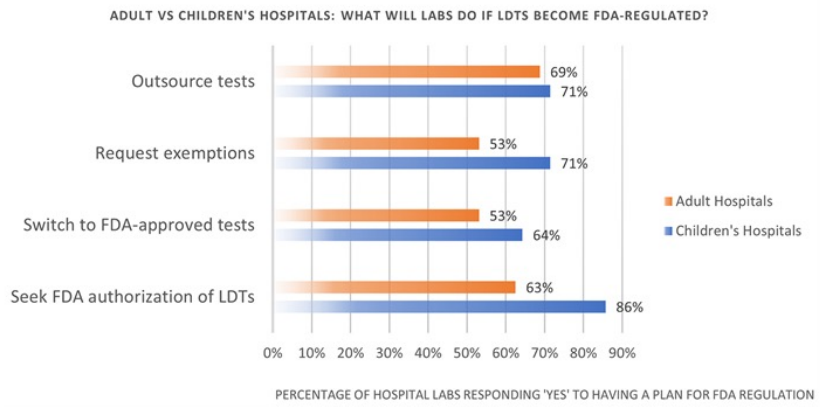
Of the 140 laboratories that responded to the survey, 87% stated they performed LDTs. Most have not, nor are they in the process of, developing a contingency plan to deal with FDA oversight. The reasons listed include the cost and administrative burden of FDA regulation, which would require them to cease performing LDTs, as well as the lack of familiarity with FDA rules compared to existing regulation under CMS.

Hospitals that have begun developing a contingency plan face a host of challenges:

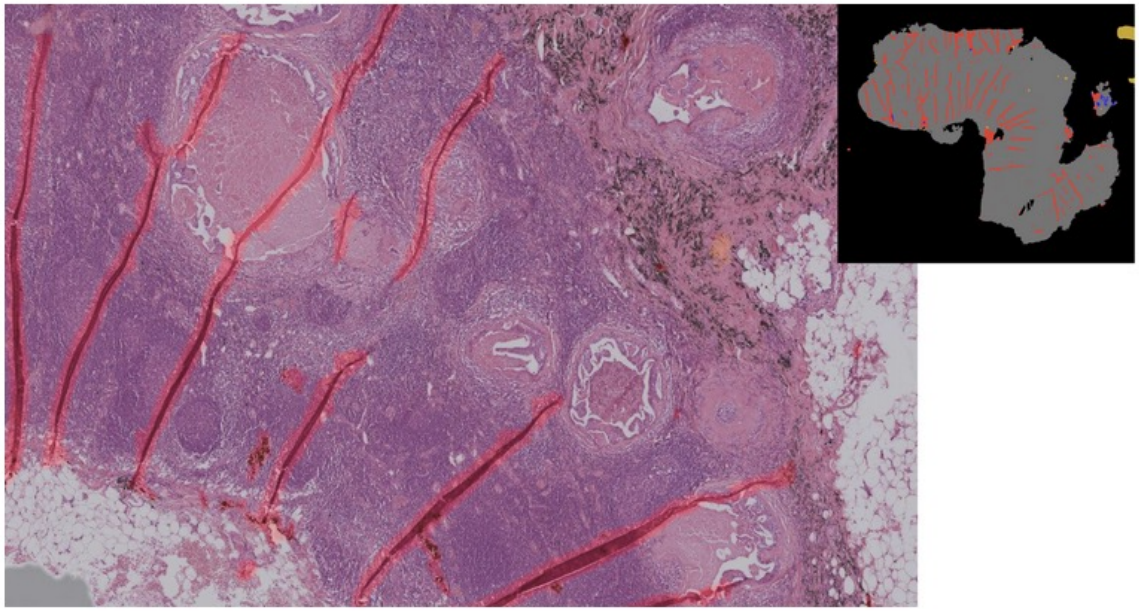
- 69% of adult hospitals and 71% of children's hospitals stated they would outsource many tests if LDTs become FDA regulated.
- More than 70% of children's hospitals stated they would seek an exemption from FDA oversight, which is not included under the current FDA proposal.
- More than half of adult and children's hospitals stated they would switch to FDA-approved tests in some instances.
- 86% of children's hospitals plan to seek FDA approval for certain LDTs.

These problems threaten to diminish the overall quality of care these hospitals provide. Outsourcing tests can delay diagnosis and treatment, which is particularly concerning for tests used to diagnose and monitor genetic disorders in infants, where every minute of delay can contribute to brain damage and the risk of severe disability. Additionally, some FDA-approved tests, such as immunoassay drug screens, are less accurate or effective at capturing relevant information than their LDT counterpart.

If LDTs become FDA-regulated, children's hospitals may be forced to make exceedingly difficult tradeoffs at the expense of patient care: To discontinue certain tests while feeling compelled to seek FDA approval for others—knowing that the cost of agency approval will likely diminish, not improve, the overall quality of care they provide.



# Publication special feature



We are a computational pathology research group
at the University Hospital Cologne
connecting clinical specialists and computer scientists.

# Fast-track development and multi-institutional clinical validation of an artificial intelligence algorithm for detection of lymph node metastasis in colorectal cancer

Avri Giammanco[1], Andrey Bychkov[2,3], Simon Schallenberg[4], Tsvetan Tsvetkov[1], Junya Fukuoka[2,3], Alexey Pryalukhin[5], Fabian Mairinger[6], Alexander Seper[5,7], Wolfgang Hulla[5], Sebastian Klein[1], Alexander Quaas[1], Reinhard Büttner[1], Yuri Tolkach[1#]