Pathology Innovation Collaborative Community

PICC

The Alliance for Digital Pathology

A collaborative community with FDA participation

Steering Committee Meeting | September 2022

FDA

U.S. FOOD & DRUG ADMINISTRATION

2022

Advancing Regulatory Science at FDA:

FOCUS AREAS OF REGULATORY SCIENCE (FARS)

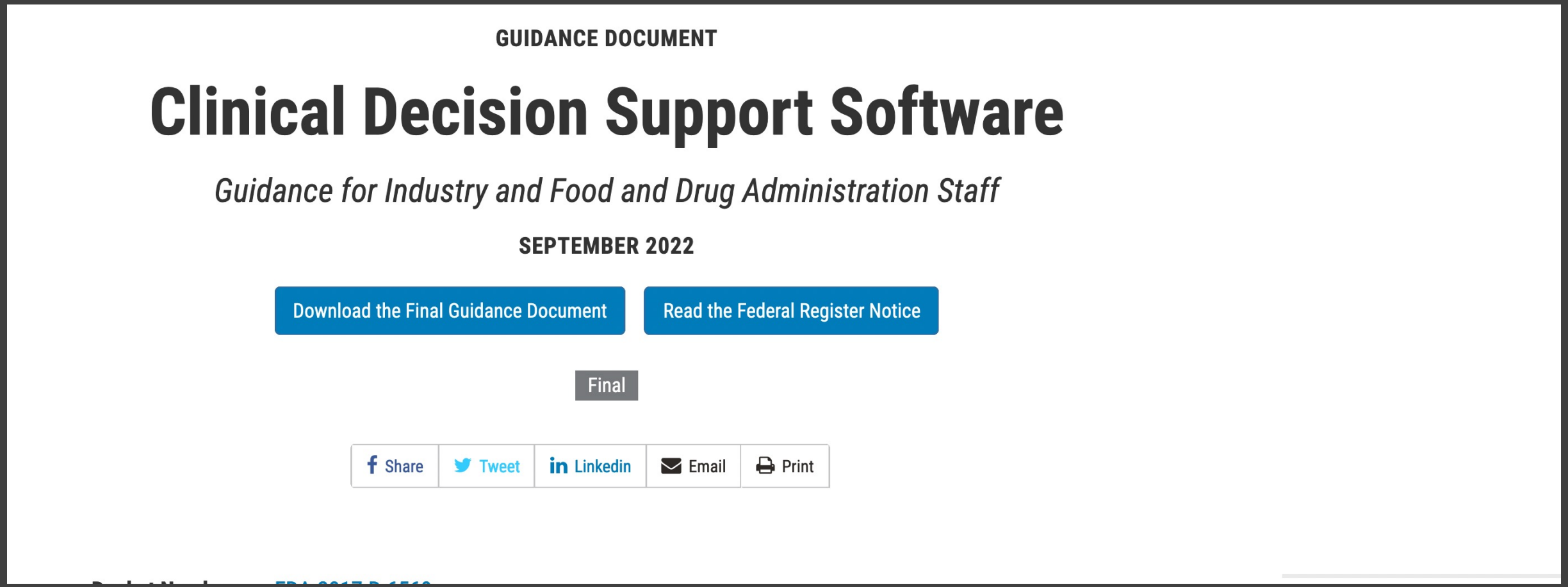
Advancing Regulatory Science at FDA

- Assessment approaches to estimate and report the robustness of AI/ML to variation in data acquisition factors.
- Technical factors influencing AI reproducibility for digital pathology applications.
- Methods for assessing the generalizability of AI performance in digital pathology applications

- Investigating the potential of AI to improve the efficiency of reviewing regulatory submissions. For example, FDA applies natural language

of our inspectional cadre, keeping
how these emerging technologies
investigations.

- Using ML to develop computer m
genomic data to predict the mean
tration (MIC) for pathogens and
surveyed for the National Antimi
Monitoring System (NARMS). Th
reliable methods to predict MICs
genome sequence data



FDA guidance
Final 9/28

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software

Interpretation of Criteria in Section 520(o)(1)(E) :C Act

lowing sections explain FDA's interpretation of each of the four criteria in sec 1)(E) of the FD&C Act. In order for a software function to be excluded from on by this provision, it must meet all four criteria. Stated simply, these criteria :s of CDS that are not regulated as devices. Non-Device CDS software functic , process, or analyze images, signals from an in vitro diagnostic device (IVD), ıls from a signal acquisition system (Criterion 1). Non-Device CDS software , analyze, or print medical information (Criterion 2) in order to provide recom patient's care to an HCP user (Criterion 3). Taken together, Criterion 1 and C e the types of data inputs used in devices (Criterion 1) and the types of data in :vice CDS (Criterion 2). Non-Device CDS software functions provide sufficie ıtion about the basis for the recommendations to the HCP user, so that the use marily on any of the recommendations to make a clinical decision about an in (Criterion 4).

FDA guidance Final 9/28

FDA Evaluation of Infant Formula Response

September 2022

Legislation

ACLA
AMERICAN CLINICAL LABORATORY ASSOCIATION

About Us COVID-19 Economic Impact Issues Take Action New

Home | Issues | Protecting Access to Medicare Act | ACLA Launches "Stop Lab Cuts" Campaign Urging Cc
Laboratory Services

ACLA LAUNCHES "STOP LAB CUTS" CAMPAIGN URGING CONGRESS TO PROTECT PATIENT ACCESS TO LABORATORY SERVICES

July 21, 2022 | Categories: Protecting Access to Medicare Act, ACLA News, All News, Featured News, ACLA Press Releases

https://stoplabcuts.org/

https://www.acla.com/acla-launches-stop-lab-cuts-campaign-urging-congress-to-protect-patient-access-to-laboratory-services/

Prior authorization

- Huge operational burden
- Cost still non-transparent

House passes bill to install electronic prior authorization in Medicare Advantage plans

By **Robert King** • Sep 14, 2022 01:27pm

Medicare Advantage | Larry Bucshon | Prior Authorization | Medical Group Management Association

The House unanimously passed legislation that installs several reforms to prior authorization in a bid to remove a key administrative burden for doctors. (Photo courtesy of Myzone)

Wednesday, September 7, 2022

The 117th Congress: Bonanza of Precision Medicine Proposals Face Legislative Cliff

http://www.discoveriesinhealthpolicy.com/2022/09/the-117th-congress-bonanza-of-precision.html

- VALID ACT = FDA oversight (see next slide)
- SALSA = guardrails around PAMA
- Medicare Multi-Cancer Early Detection Screening Coverage Act of 2021 (when FDA approved) Rep. Sewell
- Medicare: Reducing Hereditary Cancer Act
- Medicaid, prenatal genetic screening “Expanded Screening Access Act”
- Precision Medicine Answers for Kids Today Act (Peds ICU genomics)
- Right Drug Dose Now Act (Pharmacogenetics)
- Patent Eligibility Restoration Act of 2022 (diagnostic test patents)
- Find Act: Medicare Bundling in (Imaging) Diagnostics
- State Law: Biomarkers => several states passed biomarker legislation
- 21 Century Cures Act 2.0 => ARPA-H = translational medicine institute

VALID Act

Congress to Pass FDA User Fee Bill Without VALID Act, Again Putting Aside LDT Regulation

Sep 23, 2022 | staff reporter

Lawmakers attach user fees to CR, plan to revisit riders after mid-terms

Regulatory News | 27 September 2022 | By Ferdous Al-Faruque

Lawmakers have struck an eleventh-hour deal to renew the US Food and Drug Administration's (FDA) user fee programs. With just four days to go before the current programs expire, Democrats conceded to Republican demands for a "clean" reauthorization package without major riders, including diagnostics reform.

On Monday night, House and Senate lawmakers agreed to a continuing resolution (CR) that would avert a government shutdown until Congress can work out a longer-term spending bill in mid-December. The bill includes reauthorization of FDA's prescription and generic drug, biosimilar and medical device user fee programs for another five years, which means the agency will not have to lay off user-fee funded staff. (RELATED: *Convergence: CDRH will continue with MDUFA V plan even with user fee delay*,

While the inclusion of the user fee programs is a sigh of relief for FDA, the bill lacks many riders the agency was hoping to see passed alongside the reauthorization bill. That includes the long-anticipated *Verifying Accurate Leading-edge IVCT Development (VALID) Act*, which would give FDA additional authorities to regulate in vitro diagnostics (IVD), including laboratory-developed tests (LDTs).

ARPA-H

- ARPA-H will:
- Speed application and implementation of health breakthroughs to serve all patients
- Foster breakthroughs across various levels — from the molecular to the societal
- Build capabilities and platforms to revolutionize prevention, treatment, and cures in a range of diseases
- Support “use-driven” ideas focused on solving practical problems that advance equity and rapidly transform breakthroughs into tangible solutions for all patients.
- Focus on multiple time-limited projects with different approaches to achieve a quantifiable goal.
- Use a stage-gate process, with defined metrics, and inject accountability through meeting these metrics.
- Overcome market failures through critical solutions or incentives
- Use the Defense Advanced Research Projects Agency (DARPA) as a model to establish a culture of championing innovative ideas in health and medicine.


Payor Strategies

Medicare Coverage for Innovative Technology: What's the Scorecard? v2

82 views **Sep 16, 2022** Medicare is talking about updating how it approaches innovative technology. I review the activities **...more**

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Bruce Quinn
101 subscribers

https://www.youtube.com/watch?v=G5HW3S9-Xro

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JAMA Network Open

Research Letter | Health Policy

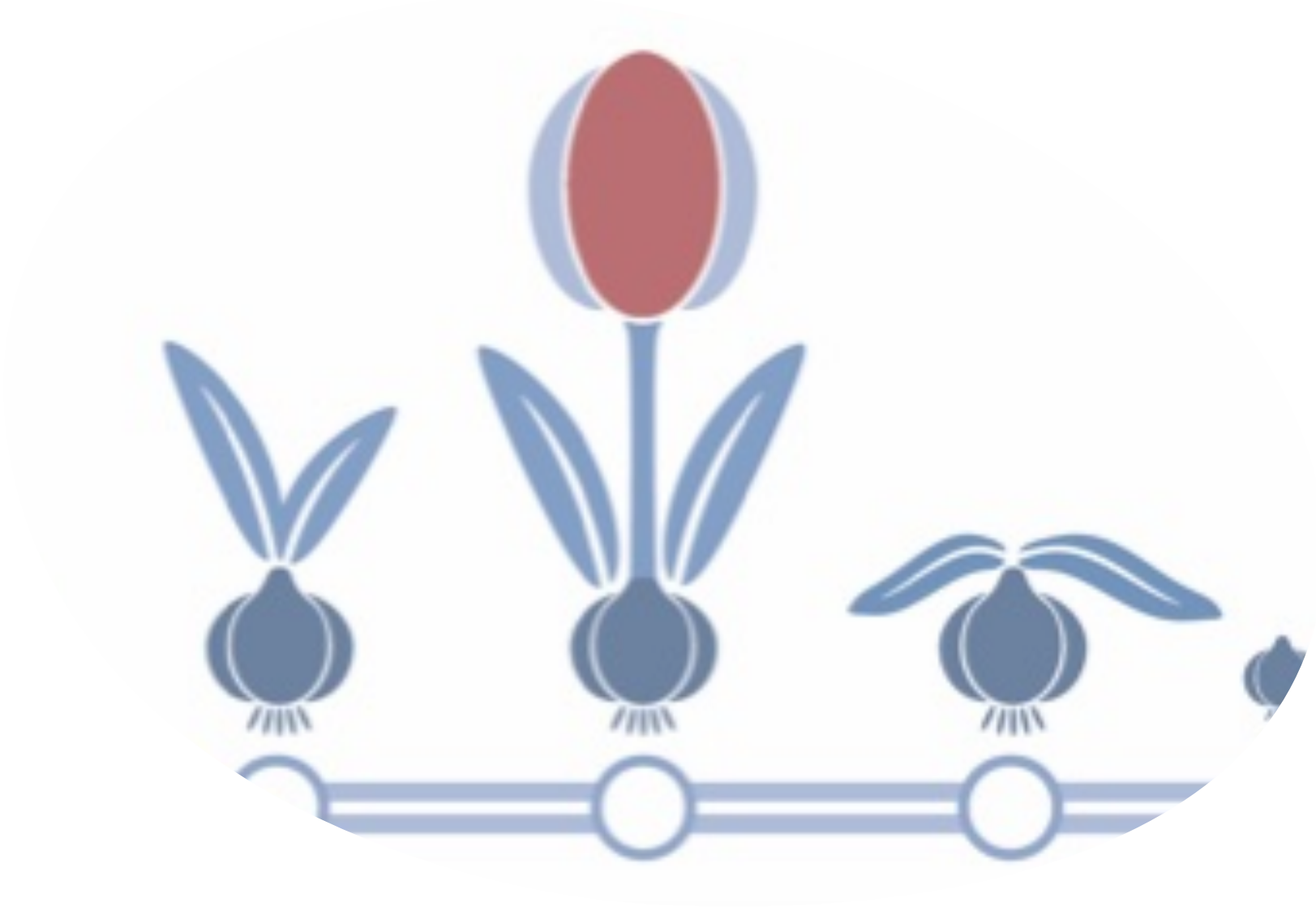
Comparison of US Hospital Cash Prices and Commercial Negotiated Prices for 70 Services

John (Xuefeng) Jiang, PhD; Martin A. Makary, MD, MPH; Ge Bai, PhD, CPA

Introduction

On January 1, 2021, the Centers for Medicare and Medicaid Services (CMS) implemented the Hospital Price Transparency Final Rule to promote price competition and improve hospital care affordability.[1] Hospitals in the US are required to disclose, among other items, the cash prices and the payer-specific negotiated prices for 70 CMS-specified, high-volume common services; however, the compliance rate has remained low.[1-3]

Author affiliations and article information are listed at the end of this article.



Payor Strategy Workgroup

Current activities (Payor Strategy Workgroup)

- **We need to educate community how to use these recently approved add-on codes:**
  - Proposal and working on PODcast with DPA and CAP
  - Recording taking place at Pathology Visions
- **PIcc webinar to create awareness and understanding:**
  - What is current landscape?
  - What is going on in Digital Health (e.g., HalioDx and Veracyt with crosswalk)?
  - How to develop more codes for DP?
    and
  - How YOU, and webinar attendees can get involved:
    e.g. set up clinical evidence study, work with DPA-Foundation to execute,…
  - *A meeting invitation will be sent soon.*
- Addressing above also to **global DPA taskforce (Japan and Europe)** to identify mutual pains and how to overcome

ESMO SCALE FOR CLINICAL ACTIONABILITY OF MOLECULAR TARGETS (ESCAT)

A framework to rank genomic alterations as targets for cancer precision medicine

A collaborative project initiated by the ESMO Translational Research and Precision Medicine Working Group provides a systematic framework to rank molecu

Implementation of a harmonised voc interpreting genomic reports and faci professionals and patients.

The ESCAT is published in 2018 in the

Related Items

Is There a Mathemetical Resolution to the Cost-Versus-Value Debate?

BRUCE FEINBERG, DO; LINCY S. LAL, PHARMD, PHD; J. MICHAEL SWINT, PHD

ABOUT THE AUTHORS

BRUCE A. FEINBERG, DO

Dr Feinberg is vice president, Clinical Affairs, and chief medical officer, Cardinal Health Specialty Solutions, Dublin, Ohio.

LINCY S. LAL, PHARMD, PHD

Dr Lal is director of HEOR, Clinical Specialty, Specialty Solutions, Cardinal Health, and lecturer, University of Texas School of Public Health in Houston.

- Restricted clinical pathways
- Product tiering
- Step edits.

Proposed policy approaches to specialty drug cost control have included, but are not limited to:

- Empowering Medicare to negotiate drug prices (as the Veteran's Administration does)
- Allowing the importation of drugs for personal use
- Reforming the patent system to combat so-called pay-for-delay settlements between brand and generic drug makers.

Solutions proposed by patient advocates and physicians aim to control costs by providing standardized approaches to valuing new drug/treatments compared with 1 or several prevailing standards of care. Increasingly, the debate over cost is transitioning to a debate over value, but the value of cancer drugs—in what is of-

tor attempts to place drug costs in line with their overall value (**FIGURES 1** and **2**). The calculator has primarily been developed as a tool for research and information only, but critics and supporters believe it "may be utilized by physicians to start a conversation discussing the value of chemotherapy agents with their patients." However, the authors clearly state it is purely informational and should not be used to guide decision making.[7]

More recently, the National Comprehensive Cancer Network (NCCN) provided a preview of its Evidence Blocks via mainstream media and its website. The Evidence Blocks, for now, are limited to multiple myeloma (MM) and chronic myeloid leukemia (CML). The NCCN Evidence Blocks are published in a new version of the NCCN Guidelines and are intended as a visual representation of 5 key value measures: efficacy,

that its appeal lies more in the convenience of a round number rather than in the current value of renal dialysis or in stakeholder assessment.[12] Nonetheless, cost-effectiveness or value analyses of healthcare interventions have an extensive history.

The confusion inherent to the casual interchangeable use of terms like quality, value, and cost-effectiveness was clarified in a seminal report published in 2002 by the Institute of Medicine (IOM), Crossing the Quality Chasm.[13] This influential work framed all future discussions of quality healthcare. In the report, IOM outlined 6 specific aims that a healthcare system must fulfill to deliver quality care:

1. **Safe:** care should be as safe for patients in healthcare facilities as in their homes.
2. **Effective:** the science and evidence behind healthcare should be ap-

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MDIC Updates

https://mdic.org/

Noor Falah, MS

- Project Manager for Cybersecurity at MDIC and PIcc
- Bench research- Effect of Neuropeptide Y on development of Ewing sarcoma
- Clinical research- Early Identification of Maternal CV Risk
- Georgetown University- MS, 2021
- George Mason University-BS, 2020
- Fun fact- avid baker

Therapeutic Innovation & Regulatory Science
https://doi.org/10.1007/s43441-022-00450-9

DIA

ANALYTICAL REPORT

Check for updates

Leveraging Patient Preference Information in Medical Device Clinical Trial Design

Liliana Rincon-Gonzalez, PhD[1] · Wendy K. D. Selig[2] · Brett Hauber, PhD[3,4] · Shelby D. Reed, PhD[5] · Michelle E. Tarver, MD, PhD[6] · Shomesh E. Chaudhuri, PhD[7] · Andrew W. Lo, PhD[8,9] · Dean Bruhn-Ding, BS[10] · Barry Liden, JD[11]

Received: 30 May 2022 / Accepted: 12 August 2022

MIDIC Publication

MDIC (in collaboration with FDA, NIST, NIH, and more) has been working to improve accuracy of next generation sequencing- based cancer diagnostics

Cybersecurity Summit: Held on 9/12, recordings available in a few weeks

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2022 Threat Modeling Bootcamps

A key piece of managing medical device and diagnostic cybersecurity risks is the integration of threat modelling (TM). TM provides a blueprint to strengthen security through the total product lifecycle of the devices, thereby ensuring improved safety and effectiveness of medical products. During the week of October 24th, 2022, please join us in attending the next round of threat–modeling bootcamps. This collaborative initiative between Shostack & Associates and MDIC aims to increase awareness on systematic approaches to TM that can enable manufacturers to effectively address system level risks. If you are unable to join us during the week of October 24th, please join us for the last threat–modeling bootcamp of 2022, held during the week of December 12th. Both bootcamps will be held over the course of 5 days, and will be led by industry experts, who helped develop the Medical Device Threat Modeling Playbook, released in 2021.

Register for the Next Threat Modeling Bootcamp!

+ **Threat Modeling Bootcamp 1: October 24-28**
+ **Threat Modeling Bootcamp 2: December 12-16**

https://mdic.org/project/2022-threat-modeling-bootcamps/#toggle-id-2-closed

MDIC Updates

- MDIC Cybersecurity Maturity Benchmarking report: To be released, October 2022
- Please contact nfalah@mdic.org or jveetil@mdic.org with any questions about MDIC initiatives

ctDNA

PRECISION MEDICINE

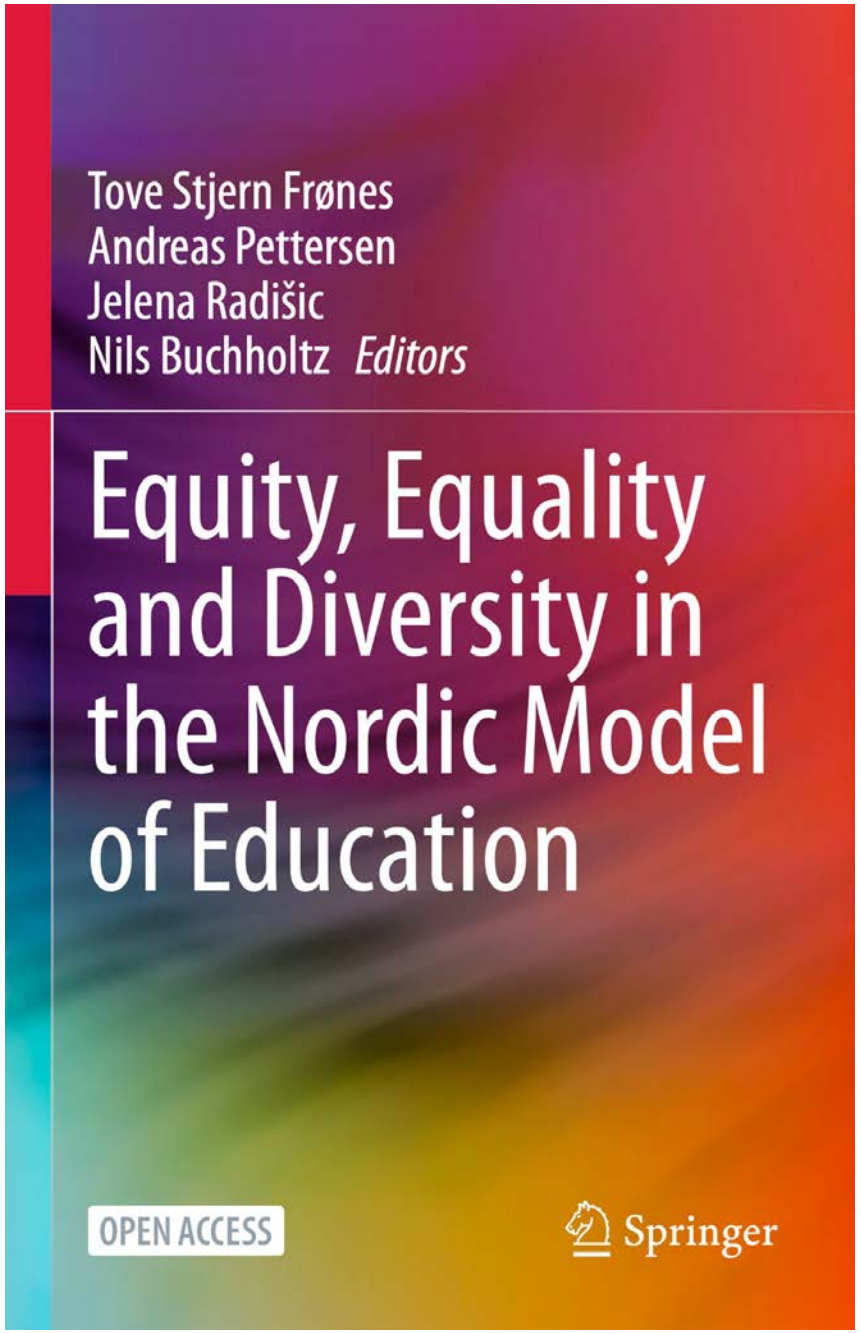
Changes in Circulating Tumor DNA Reflect Clinical Benefit Across Multiple Studies of Patients With Non–Small-Cell Lung Cancer Treated With Immune Checkpoint Inhibitors

Diana Merino Vega, PhD[1]; Katherine K. Nishimura, PhD, MPH[2]; Névine Zariffa, PhD[3]; Jeffrey C. Thompson, MD[4]; Antje Hoering, PhD[2]; Vanessa Cilento, MPH[2]; Adam Rosenthal, MS[2]; Valsamo Anagnostou, MD, PhD[5]; Jonathan Baden, MS[6]; Julia A. Beaver, MD[7]; Aadel A. Chaudhuri, MD, PhD[8,9,10,11]; Darya Chudova, PhD[12]; Alexander D. Fine, PhD[13]; Joseph Fiore, PharmD[14]; Rachel Hodge, PhD[15]; Darren Hodgson, PhD[16]; Nathan Hunkapiller, PhD[17,18]; Daniel M. Klass, PhD[19]; Julie Kobie, PhD[20]; Carol Peña, PhD[21]; Gene Pennello, PhD, MS[22]; Neil Peterman, PhD[23]; Reena Philip, PhD[24]; Katie J. Quinn, PhD[12]; David Raben, MD[25]; Gary L. Rosner, ScD[5]; Mark Sausen, PhD[6]; Ayse Tezcan, MPH, PhD[23]; Qi Xia, PhD[26]; Jing Yi, PhD[25]; Amanda G. Young, PhD[13]; Mark D. Stewart, PhD[1]; Erica L. Carpenter, MBA, PhD[27]; Charu Aggarwal, MD, MPH[27]; and Jeff Allen, PhD[1]

original reports abstra

PURPOSE As immune checkpoint inhibitors (ICI) become increasingly used in frontline settings, identifying early indicators of response is needed. Recent studies suggest a role for circulating tumor DNA (ctDNA) in monitoring response to ICI, but uncertainty exists in the generalizability of these studies. Here, the role of ctDNA for monitoring response to ICI is assessed through a standardized approach by assessing clinical trial data from five

Diversity & Inclusion


Tove Stjern Frønes
Andreas Pettersen
Jelena Radišic
Nils Buchholtz Editors
Equity, Equality and Diversity in the Nordic Model of Education
OPEN ACCESS
Springer

Annals of Internal Medicine

ORIGINAL RESEARCH

Quantifying Individual-Level Inaccuracy in Glomerular Filtration Rate Estimation

A Cross-Sectional Study

Tariq Shafi, MBBS, MHS*; Xiaoqian Zhu, PhD*; Seth T. Lirette, PhD; Andrew D. Rule, MD; Thomas Mosley, PhD; Kenneth R. Butler, PhD; Michael E. Hall, MD, MS; Pradeep Vaitla, MD; James J. Wynn, MD; Maria Clarissa Tio, MD, MPH; Neville R. Dossabhoy, MD; Eliseo Guallar, MD, DrPH; and Javed Butler, MD, MPH, MBA

Background: Although the population-level differences between estimated glomerular filtration rate (eGFR) and measured glomerular filtration rate (mGFR) are well recognized, the magnitude and potential clinical implications of individual-level differences are unknown.

Objective: To quantify the magnitude and consequences of the individual-level differences between mGFRs and eGFRs.

Design: Cross-sectional study.

Setting: Four U.S. community-based epidemiologic cohort studies with mGFR.

Patients: 3223 participants in 4 studies.

Measurements: The GFRs were measured using urinary iothalamate and plasma iohexol clearance; the eGFR was calculated from 52 to 67, 80% from 45 to 76, and 95% from 36 to 87. At an $eGFR_{CR}$ of 30, 50% of mGFRs ranged from 27 to 38, 80% from 23 to 44, and 95% from 17 to 54. Substantial disagreement in chronic kidney disease staging by mGFR and $eGFR_{CR}$ was present. Among those with $eGFR_{CR}$ of 45 to 59, 36% had mGFR greater than 60 whereas 20% had mGFR less than 45; among those with $eGFR_{CR}$ of 15 to 29, 30% had mGFR greater than 30 and 5% had mGFR less than 15. The eGFR based on cystatin C did not provide substantial improvement.

Limitation: Single measurement of mGFR and serum markers without short-term replicates

Conclusion: A substantial individual-level discrepancy exists between the mGFR and the eGFR. Laboratories reporting eGFR should consider including the extent of this uncertainty to avoid misinterpretation of eGFR as an mGFR replacement.

U.S. Department of Health and Human Services

Office of Inspector General

Data Brief

September 2022, OEI-02-20-00522

Certain Medicare Beneficiaries, Such as Urban and Hispanic Beneficiaries, Were More Likely Than Others To Use Telehealth During the First Year of the COVID-19 Pandemic

Key Takeaways

- Beneficiaries in urban areas were more likely than those in rural areas to use telehealth.
- Dually eligible, Hispanic, younger, and female beneficiaries were also more likely than others to use telehealth.

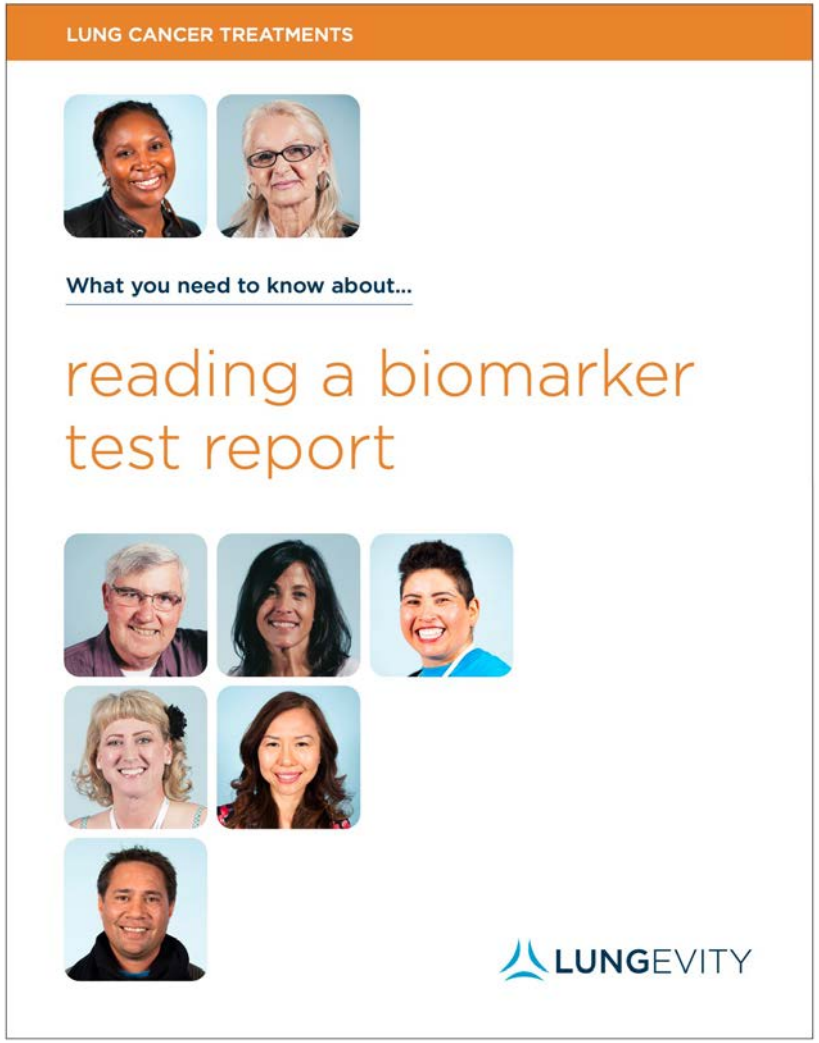
Why OIG Did This Review

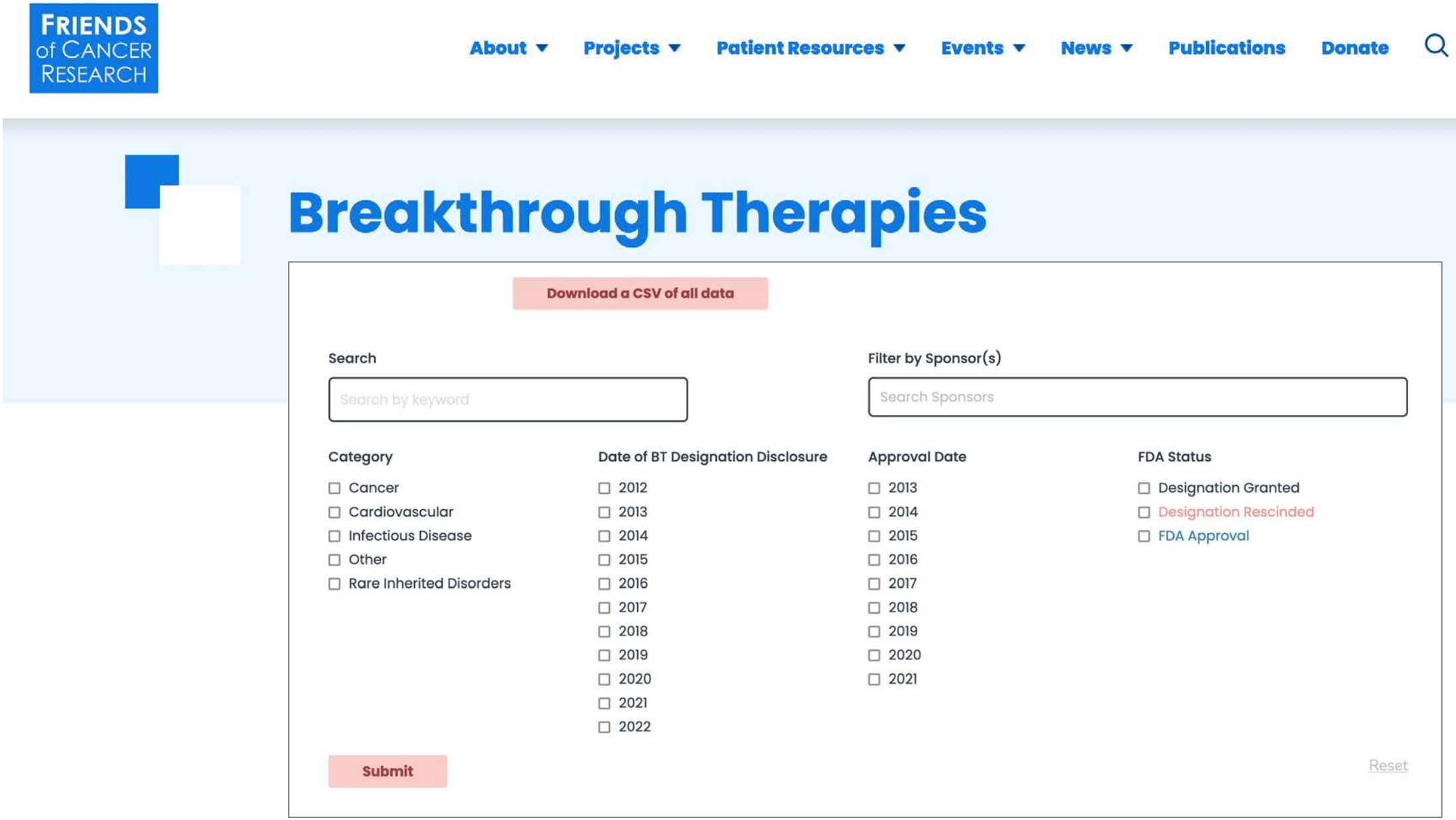
The COVID-19 pandemic created unprecedented challenges for how Medicare beneficiaries access health care. In response, the Department of Health and Human Services (HHS) and the Centers for Medicare & Medicaid Services (CMS) took a number of actions to temporarily expand access to telehealth for Medicare beneficiaries.[1] CMS allowed beneficiaries to use telehealth for a wide range of services and in different locations, including in urban areas and from the beneficiary's home.

In a companion report, OIG found that the use of telehealth increased

Resources

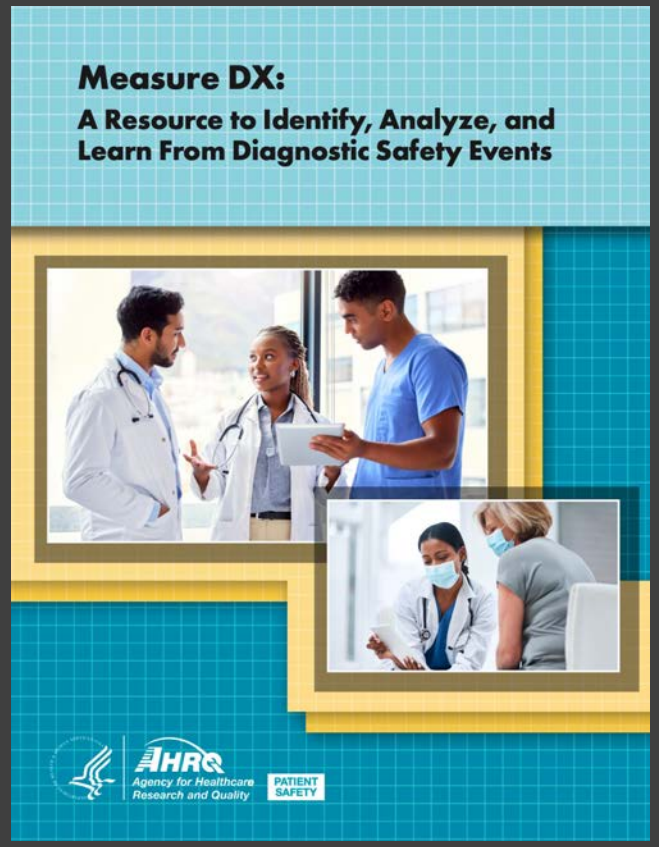
LUNGEVITY

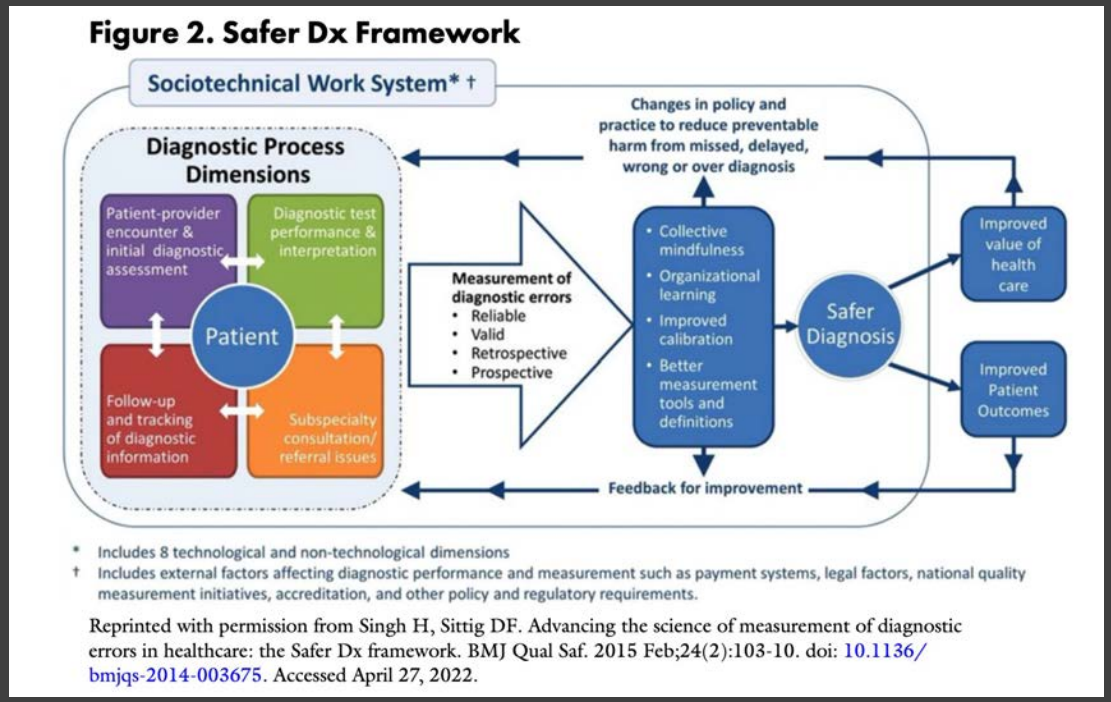

LUNG CANCER TREATMENTS
What you need to know about...
reading a biomarker test report
LUNGEVITY



https://friendsofcancerresearch.org/breakthrough-therapies/

Diagnostic Error Resource





ARHQ resource

- 57 page .pdf
- Safer Dx Framework
- Excellent “quality management” resource

Quality

- https://www.abqaurp.org/ABQMain/Certification/Overview_of_HCQM_Certification/ABQMain/Certification.aspx?hkey=b6edc3b2-6da9-49d0-a824-3399badf629e

correspondence

Choosing Wisely for oncology in Brazil: 10 recommendations to deliver evidence-based cancer care

To the Editor — Brazil is the largest country in South America and has a high incidence of cancer. There were an estimated 625,000 new cancer cases in 2020, representing a 17% increase compared to 2012, when there

Table 1 | Top 10 recommendations from the Choosing Wisely Brazil oncology task force

Item #	Recommendation	Source	Phase of cancer journey

Short 3 page paper

- Provides 10 high-yield recommendations
- Focus “Brazil” – but applicable beyond
- Oncology Task force

Check for updates

PRECISION MEDICINE

review articles

An Approach to Solving the Complex Clinicogenomic Data Landscape in Precision Oncology: Learnings From the Design of WAYFIND-R, a Global Precision Oncology Registry

Christophe Le Tourneau, MD, PhD[1]; Camille Perret, PhD[2]; Allan Hackshaw, PhD[3]; Jean-Yves Blay, MD, PhD[4]; Christoph Nabholz, PhD[5]; Jan Geissler, MBA[6]; Thy Do, PhD[2,7]; Martina von Meyenn, PhD[2]; and Rodrigo Dienstmann, MD[8,9]

abstract

Precision oncology, where patients are given therapies based on their genomic profil
rapidly evolving to become a pivotal part of cancer management, supported by regulat
matched targeted therapies and cancer immunotherapies. However, next-generation
technologies have revealed an increasing number of molecular-based cancer subty
ulations, leading to difficulties in executing/recruiting for traditional clinical trials. Th
therapeutics based on traditional interventional studies may be difficult and time consu
to innovative therapies. Real-world data (RWD) that describe the patient journey in r

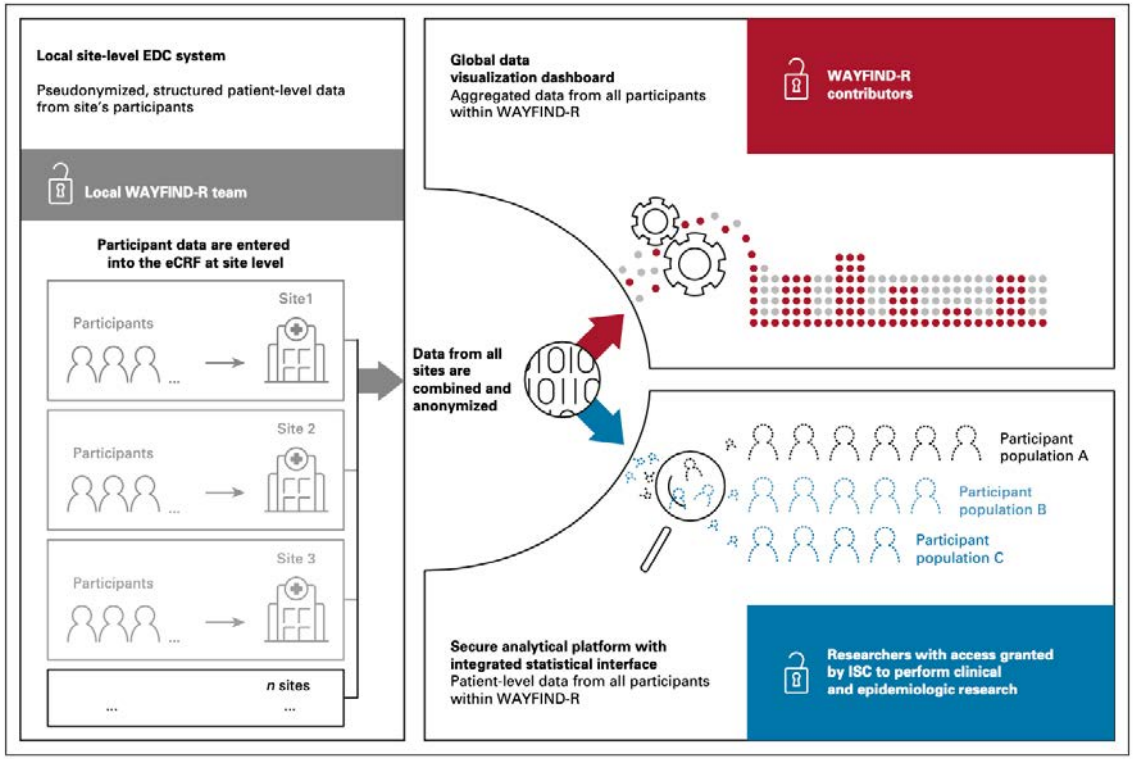


FIG 3. WAYFIND-R data sharing and access framework. A signed and dated informed consent form is obtained from patients. eCRF, electronic case report form; EDC, electronic data capture; ISC, independent scientific committee.

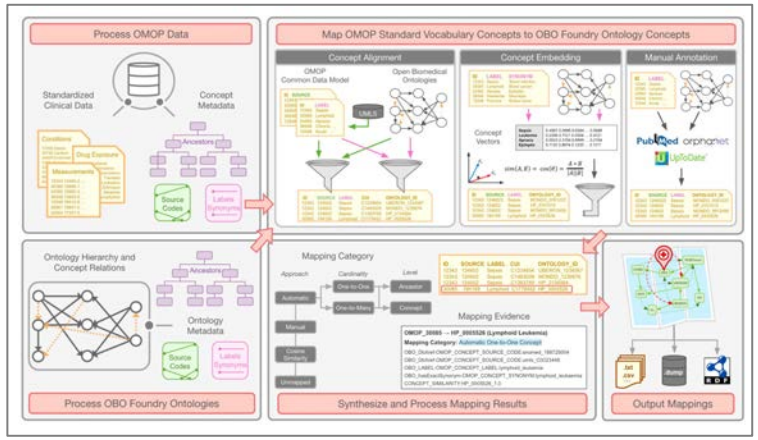
“Data Model”

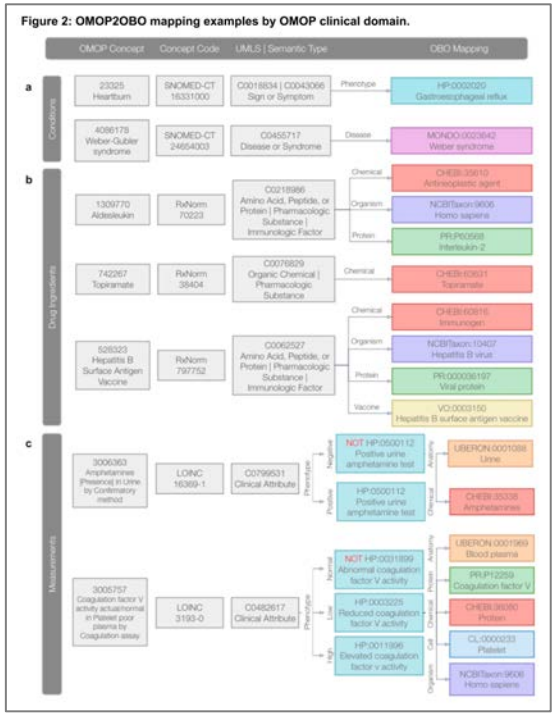
- Ontologizing Health System Data is a challenge
- Pre-print (Callahan et al.,)
- Translational Discover Focus

https://arxiv.org/ftp/arxiv/papers/2209/2209.04732.pdf

Ontologizing Health Systems Data at Scale: Making Translational Discovery a Reality

Tiffany J. Callahan[1,2*], Adrianne L. Stefanski[1], Jordan M. Wyrwa[3], Chenjie Zeng[4], Anna Ostropolets[2], Juan M. Banda[5], William A. Baumgartner Jr.[1], Richard D. Boyce[6], Elena Casiraghi[7], Ben D. Coleman[8], Janine H. Collins[9], Sara J. Deakyne-Davies[10], James A. Feinstein[11], Melissa A. Haendel[12], Asiyah Y. Lin[4], Blake Martin[13], Nicolas A. Matentzoglu[14], Daniella Meeker[15], Justin Reese[16], Jessica Sinclair[17], Sanya B. Taneja[18], Katy E. Trinkley[19], Nicole A. Vasilevsky[20], Andrew Williams[21], Xingman A. Zhang[22], Peter N. Robinson[8], Patrick Ryan[23], George Hripcsak[2], Tellen D. Bennett[13], Lawrence E. Hunter[1,24], Michael G. Kahn[24]





Special Report

EXPERT REVIEWS

Teaching medical device design using design control

Expert Rev. Med. Devices 9(1), 7–14 (2012)

Karen May-Newman*[1] and G Bryan Cornwall[2]

[1]Bioengineering Program, College of Engineering, San Diego State University, San Diego, CA 9218, USA
[2]Research and Clinical Resources, NuVasive, Inc., 7475 Lusk Blvd, San Diego, CA 92121, USA
**Author for correspondence: kmaynewm@mail.sdsu.edu*

The design of medical devices requires an understanding of a large number of factors, many of which are difficult to teach in the traditional educational format. This subject benefits from using a challenge-based learning approach, which provides focused design challenges requiring students to understand important factors in the context of a specific device. A course was designed at San Diego State University (CA, USA) that applied challenge-based learning through in-depth design challenges in cardiovascular and orthopedic medicine, and provided an immersive field, needs-finding experience to increase student engagement in the process of knowledge acquisition. The principles of US FDA 'design control' were used to structure the students' problem-solving approach, and provide a format for the design documentation, which was the basis of grading. Students utilized a combination of lecture materials, industry guest expertise, texts and readings,

JAMA Network Open

Original Investigation | Oncology

Analysis of Cancer Survival Associated With Immune Checkpoint Inhibitors After Statistical Adjustment

A Systematic Review and Meta-analyses

Emily Pei-Ying Lin, MD, PhD; Chih-Yuan Hsu, PhD; Lynne Berry, PhD; Paul Bunn, MD; Yu Shyr, PhD

Abstract

IMPORTANCE Appropriate clinical decision-making relies on accurate data interpretation, which in turn relies on the use of suitable statistical models. Long tails and early crossover—2 features commonly observed in immune checkpoint inhibitor (ICI) survival curves—raise questions as to the suitability of Cox proportional hazards regression for ICI survival analysis. Cox proportional hazards–Taylor expansion adjustment for long-term survival data (Cox-TEL) adjustment may provide possible solutions in this setting.

OBJECTIVE To estimate overall survival and progression-free survival benefits of ICI therapy vs chemotherapy using Cox-TEL adjustment.

DATA SOURCES A PubMed search was performed for all cataloged publications through May 22, 2022.

Key Points

Question Is there a difference in survival outcomes associated with immune checkpoint inhibitor therapy compared with chemotherapy when corrected for error introduced by Cox proportional hazards analysis?

Findings In this systematic review and meta-analysis of 13 clinical trials across 3 cancer types (non–small-cell lung cancer, urothelial carcinoma, and melanoma), the Cox proportional hazards–Taylor expansion adjustment

nature immunology

REVIEW ARTICLE

https://doi.org/10.1038/s41590-022-01309-9

Check for updates

A guide to systems-level immunomics

Lorenzo Bonaguro[1,2,3,6], Jonas Schulte-Schrepping[1,2,3,6], Thomas Ulas[1,2,3,6], Anna C. Aschenbrenner[1,2,4], Marc Beyer[1,2,5] and Joachim L. Schultze[1,2,3] ✉

The immune system is highly complex and distributed throughout an organism, with hundreds to th in parallel with diverse molecular pathways interacting in a highly dynamic and coordinated fashio tion of individual genes and molecules is of the utmost importance for understanding immune-syste

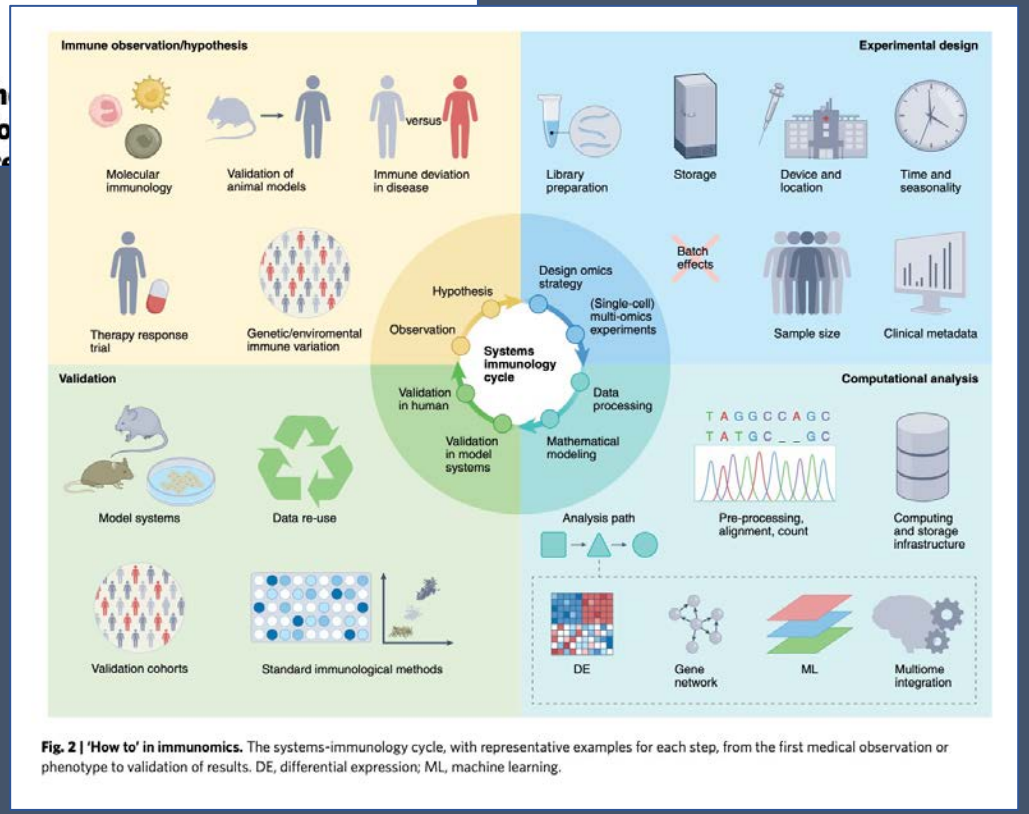


Fig. 2 | 'How to' in immunomics. The systems-immunology cycle, with representative examples for each step, from the first medical observation or phenotype to validation of results. DE, differential expression; ML, machine learning.

Publications

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journal homepage: www.ejcancer.com

Current Perspective

Selecting patients with HER2-low breast cancer: Getting out of the tangle

Ximena Baez-Navarro [a,*], Roberto Salgado [b,c], Carsten Denkert [e], Jochen K. Lennerz [h], Frédérique Penault-Llorca [f], Giuseppe Viale [g], John M.S. Bartlett [d], Carolien H.M. van Deurzen [a]

[a] *Department of Pathology, Erasmus MC, Rotterdam, the Netherlands*
[b] *Department of Pathology, GZA-NZA Hospitals, Antwerp, Belgium*
[c] *Division of Research, Peter MacCallum Cancer Centre, Melbourne, Australia*
[d] *Cancer Research UK Edinburgh Centre, Institute of Genetics and Cancer, The University of Edinburgh, Edinburgh, UK*
[e] *Institute of Pathology, Philipps-University Marburg and University Hospital Marburg (UKGM), Baldingerstr. 1, 35043*

https://doi.org/10.1038/d41586-022-02041-y

News & views

Pharmacology

Two-drug trick to block systemic toxicity

Matthias P. Wymann & Chiara Borsari

When combined, two drugs alter the activity of a protein complex called target of rapamycin complex 1 such that it is inhibited in the brain but not the body, enabling the treatment of brain tumours in mice without systemic toxicity.

Medicinal chemists and pharmacologists

rapamycin. Because the FKBP12–rapamycin

chemical libraries of molecules based on a synthetic ligand of FKBP12 called SLF, and the higher-affinity natural ligand (FK506). The authors then tested the resulting molecules for their ability to block the inhibition of TORC1 either by rapamycin or by its derivative RapaLink-1. RapaLink-1 is composed of rapamycin linked to an mTOR kinase inhibitor (which binds to mTOR's catalytic ATP-binding pocket[5]). By engaging both the FRB domain and the ATP-binding site, RapaLink-1 binds to TORC1 exceptionally tightly.

Zhang *et al.* found that rapamycin could be impeded by the low-affinity SLF derivatives, but that RapaLink-1 was substantially intercepted only by the higher-affinity FK506 derivatives. They therefore selected an FK506 derivative as RapaBlock, which integrates three key properties: first, it has a high

Outline

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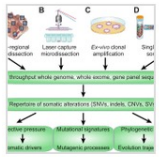
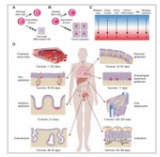
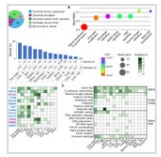
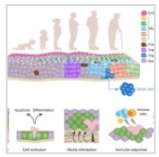
Figures (4)









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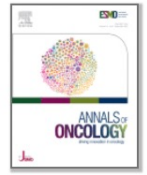


Review

Somatic variation in normal tissues: friend or foe of cancer early detection?

A. Acha-Sagredo [1, 2, †], P. Ganguli [1, 2, †], F.D. Ciccarelli [1, 2]

Show more

https://doi.org/10.1016/j.annonc.2022.09.156

HIGHLIGHTS

- Somatic tissues become a patchwork of mutant clones as we age
- The extent of somatic variation depends on tissue features and exposure to insults

2022 ASCO ANNUAL MEETING
ADVANCING EQUITABLE CANCER CARE THROUGH INNOVATION

Image-Based Detection of *FGFR3*-Mutations & Fusion in Urothelial Bladder Cancer

Nir Peled[1], Jonathan Zalach[2], Inbal Gazy[2], Ido Hayun[2], Assaf Avinoam[2], Tilda Barliya[2], Nurit Paz-Yaacov[2]

[1]Shaare Zedek Medical Center, Jerusalem , Israel [2]Imagene AI, Tel Aviv, Israel

Introduction

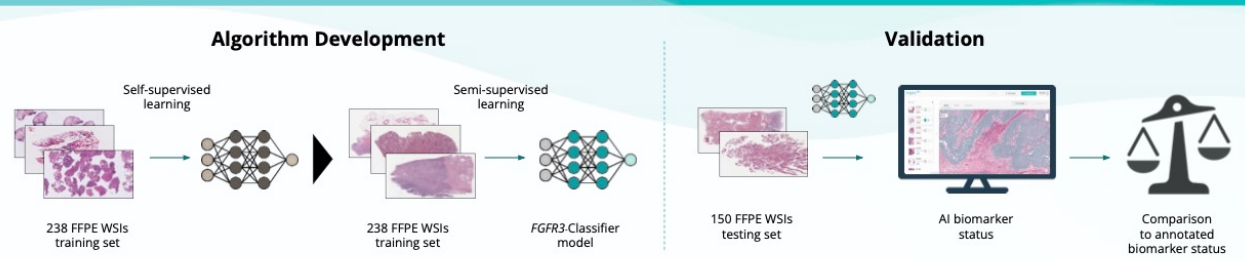
- Fibroblast Growth Factor Receptor 3 (*FGFR3*) is a prognostic, predictive and therapeutic target in Urothelial Bladder Cancer (UC).
- *FGFR3* alterations are found in ~15-30% of UC cases.
- Mutations occur in 12-80% of cases (depending on grade and stage).
- Fusions are less frequent, with *TACC3* being the most common partener and found in 2-6% of UC.
- Erdafitinib is an *FGFR2/3* kinase inhibitor used to treat advanced stages UC patients:
  - Approved indications include point mutations in *FGFR3* (R248C, S249C, G370C, Y373C) and *FGFR3-TACC3* fusions.
  - Response rate is significantly higher in patients carrying mutations compared to those with fusions.

Aim

To develop and validate image-based model for the detection of *FGFR3* alterations directly from routine pathology Hematoxylin and Eosin (H&E) scanned slides, using deep learning (DL) algorithms.

Method

- 388 H&E whole slide images (WSIs) of UC samples, obtained from the TCGA Research Network (https://www.cancer.gov/tcga) were used.
- Cases were randomly divided into training (n=238) and testing (n=150) sets.
- Advanced Convolutional Neural Network (CNN) was used to generate the *FGFR3*-Classifier on the training set following validation on the testing set.



Results

- Validation of the *FGFR3*-Classifier was performed on 150 cases from 19 different centers.
- The cohort included a total of 20 positive cases (17 actionable *FGFR3* mutations and 3 *FGFR3-TACC3* fusion cases).
- The *FGFR3*-Classifier performance was measured in comparison to the TCGA dataset annotations.

	Official Results		*FGFR3*-Classifier Results				*FGFR3*-Classifier Performance			
Total	**P**	**N**	**TP**	**TN**	**FP**	**FN**	**Sensitivity**	**Specificity**	**Accuracy**	**AUC**
n=150	20	130	19	111	19	1	95%	85.4%	86.7%	0.93

P- Positive, N- Negative, TP- true positive, TN- true negative, FP- false positive, FN- false negative, AUC- area under curve

Conclusion

- Herein, we described an AI-based solution for *FGFR3* alterations (mutations and fusions) identification in Urothelial Cancer.
- Integration of such a solution into the routine pathological pipeline can facilitate accurate, fast and systemic screening of UC patients, to support treatment optimization.
- This AI-based solution can predict biomarker status directly from H&E stained slide images, without the need for any additional tissue.
- Utilization of such an AI-based tool can support real-time molecular analysis of different types of alterations in cancers originating from a wide range of organs.

VIEWPOINT

DIAGNOSTIC EXCELLENCE

Decoding Artificial Intelligence to Achieve Diagnostic Excellence
Learning From Experts, Examples, and Experience

Jonathan H. Chen, MD, PhD
Stanford Center for Biomedical Informatics Research, Division of Hospital Medicine, Stanford University, Stanford, California.

Gurpreet Dhaliwal, MD
Department of Medicine, University of California, San Francisco; and Medical Service, San Francisco Veteran Affairs Medical Center, San Francisco,

Clinical decision support systems that use artificial intelligence (AI) to improve diagnostic accuracy, efficiency, and safety have long been aspirational goals for computer scientists and clinicians. Yet diagnostic AI development has seen multiple cycles of inflated peaks of expectations followed by troughs of disillusionment. Clinicians are understandably wary of embracing new diagnostic AI solutions without understanding how they work and relate to their existing practice.

Diagnostic AI refers to a broad range of applications that use learning strategies that mimic human approaches to learning. When clinicians understand the underlying mechanisms of diagnostic AI, they can become informed users of these tools, appreciating both their advantages and limitations. This Viewpoint outlines 3 learning methods that

effort of human experts to manually encode thousands of rules is poorly suited for a complex adaptive field like medicine in which rules can contradict each other and regularly become obsolete in the face of new knowledge.[2]

Training these early AI systems by encoding knowledge rules resembles the learning process for physicians early in their careers. Medical students learn from their teachers (experts) and mimic their diagnostic thinking and rules (eg, "if fever, cough, and pulmonary infiltrate, then diagnose pneumonia").

Learning From Examples

Most recent popular applications of diagnostic AI rely on supervised machine learning, which discerns patterns from example cases labeled by humans with the "correct" an-

VIEWPOINT

DIAGNOSTIC EXCELLENCE

Rethinking Algorithm Performance Metrics for Artificial Intelligence in Diagnostic Medicine

Matthew A. Reyna, PhD, MS
Department of Biomedical Informatics, Emory University, Atlanta, Georgia.

Elaine O. Nsoesie, PhD
Department of Global Health, School of Public Health, Boston University, Boston, Massachusetts.

The promise of artificial intelligence (AI) to improve and reduce inequities in access, quality, and appropriateness of high-quality diagnosis remains largely unfulfilled. Vast clinical data sets, extensive computational capacity, and highly developed and accessible machine-learning tools have resulted in numerous publications that describe high-performing algorithmic approaches for a variety of diagnostic tasks. However, such approaches remain largely unadopted in clinical practice.

This discrepancy between promise and practice—the AI chasm—has many causes. Some reasons are endemic to the larger field of AI, including a lack of generferent metrics. Two such metrics, developed for a series of public competitions known as the PhysioNet Challenges, illustrate these issues.

For the 2019 PhysioNet Challenge, teams were asked to develop algorithms for early sepsis prediction.[1] The algorithms made hourly sepsis predictions to identify patients for treatment up to 12 hours before clinical recognition of sepsis onset. A time-dependent performance metric was designed to reward or penalize algorithms, depending on the clinical utility of their predictions and their likelihood of improving patient outcomes.[1] This metric provided high scores for early

Research

JAMA Dermatology | Original Investigation

Real-time Analysis of Skin Biopsy Specimens With 2-Photon Fluorescence Microscopy

Vincent D. Ching-Roa, MS; Chi Z. Huang, MS; Sherrif F. Ibrahim, MD, PhD; Bruce R. Smoller, MD; Michael G. Giacomelli, PhD

IMPORTANCE Nonmelanoma skin cancers (NMSCs) are primarily diagnosed through paraffin section histologic analysis of skin biopsy specimens that requires days to weeks before a formal diagnosis is reported. Two-photon fluorescence microscopy (TPFM) has the potential for point-of-care diagnosis of NMSC and other dermatologic conditions, which could enable same-visit diagnosis and treatment.

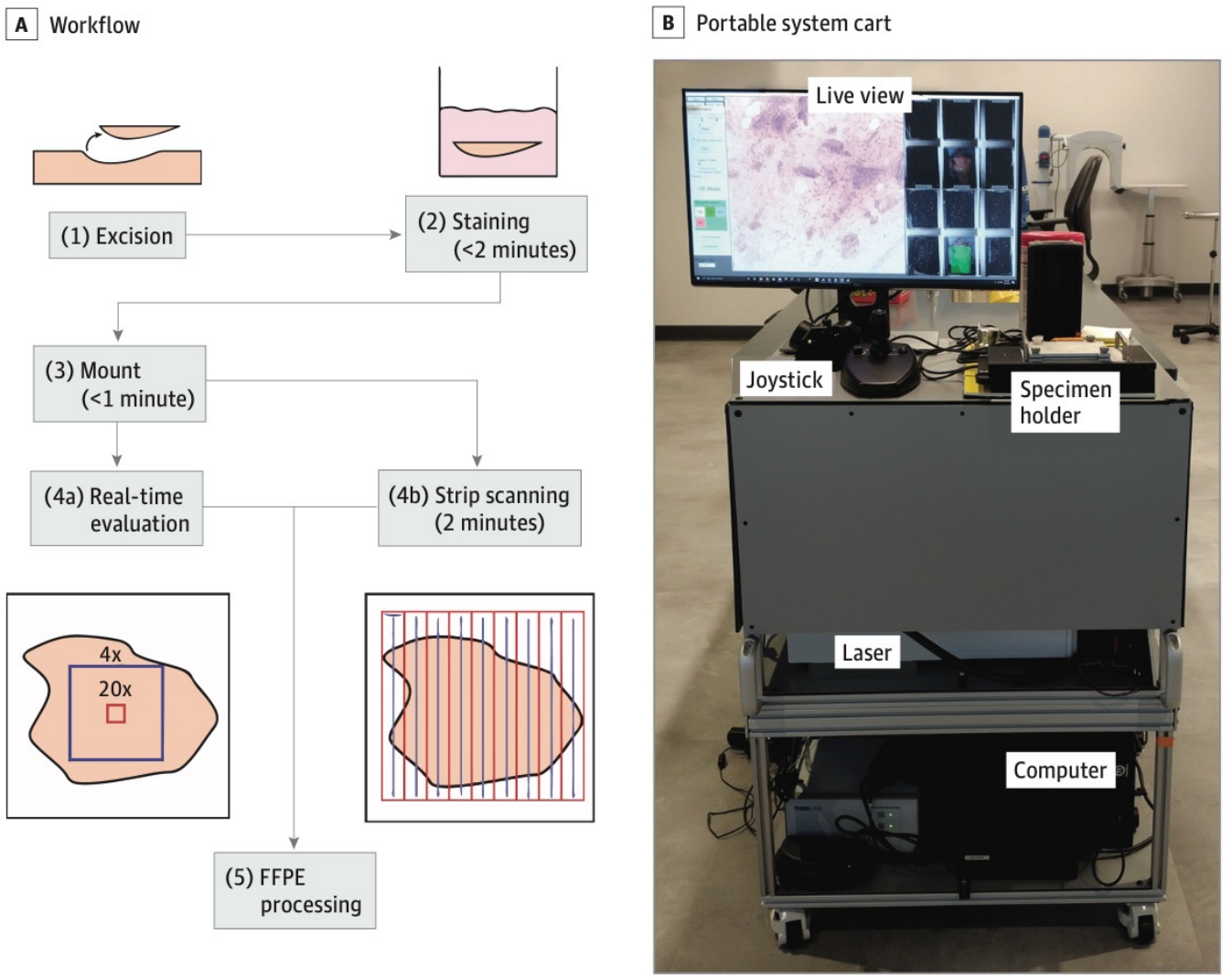
OBJECTIVE To demonstrate that TPFM imaging of NMSC can occur within minutes of obtaining biopsies and provide similar histological features to those of conventional histology and evaluate TPFM diagnostic performance with respect to conventional histology.

DESIGN, SETTING, AND PARTICIPANTS This comparative effectiveness pilot study examined 29 freshly excised biopsies from confirmed NMSC lesions in patients presenting for treatment. Biopsies underwent imaging immediately with TPFM on site at Rochester Dermatologic

Editorial

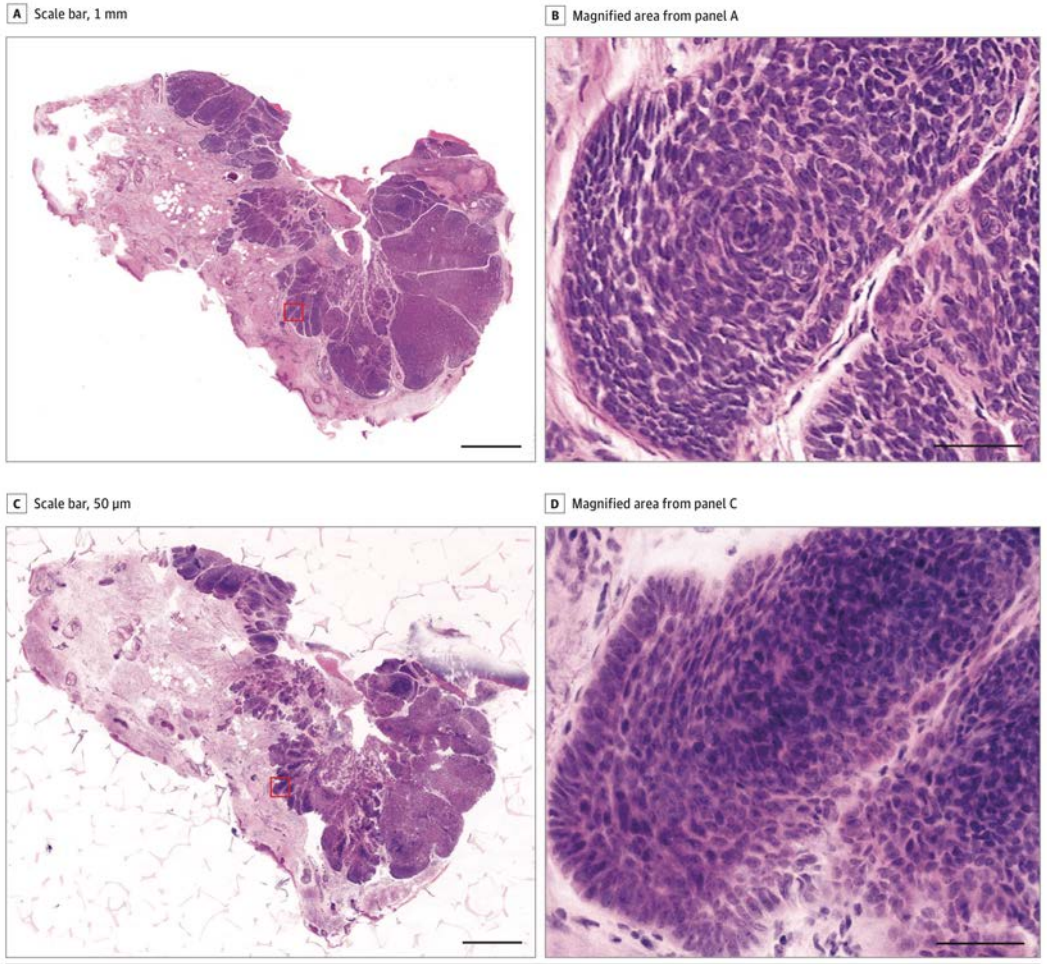
Supplemental content

Figure 1. Clinical 2-Photon Fluorescence Microscopy (TPFM) Workflow and Portable System Cart



A, Workflow for biopsy specimens used in this study. Excisions are ready to undergo imaging within 2 to 3 minutes. Real-time evaluation mode allows the 4× (blue box) and 20× field (red box) to be panned. Strip scanning acquires a full tissue mosaic in around 2 minutes. B, Clinic-based TPFM showing the physical user interface with live-view monitor and joystick for movement, while optical components, laser, and computer are enclosed in the cart.

Figure 2. Nodular Basal Cell Carcinoma



Full field brightfield image of a nodular basal cell carcinoma shave biopsy (A) and Magnified image of a region highlighted by the red box from panel A (B). The TPFM image of the same biopsy (C) and magnified region from panel C (D). (Scale bars: 1 mm [A and C], 50 µm [B and D]). Full H&E image: https://imstore.circ.rochester.edu/papers/jama2022/fig2/slide/zstack.html. Full TPFM image: https://imstore.circ.rochester.edu/papers/jama2022/fig2/tpfm/zstack.html

Research

JAMA Dermatology | Original Investigation

Real-time Analysis of Skin Biopsy Specimens With 2-Photon Fluorescence Microscopy

Vincent D. Ching-Roa, MS; Chi Z. Huang, MS; Sherrif F. Ibrahim, MD, PhD; Bruce R. Smoller, MD; Michael G. Giacomelli, PhD

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DESIGN, SETTING, AND PARTICIPANTS This comparative effectiveness pilot study examined 29 freshly excised biopsies from confirmed NMSC lesions in patients presenting for treatment. Biopsies underwent imaging immediately with TPFM on site at Rochester Dermatologic

Editorial

Supplemental content

JAMA Surgery | Original Investigation

Real-time Tracking and Classification of Tumor and Nontumor Tissue in Upper Gastrointestinal Cancers Using Diffuse Reflectance Spectroscopy for Resection Margin Assessment

Scarlet Nazarian, MBBS, BSc; Ioannis Gkouzionis, MEng; Michal Kawka, BSc; Marta Jamroziak, BSc; Josephine Lloyd, MA; Ara Darzi, MD; Nisha Patel, MBBS, BSc, PhD; Daniel S. Elson, PhD; Christopher J. Peters, PhD

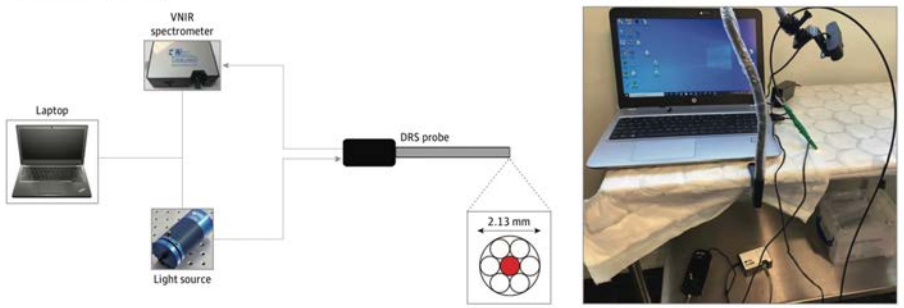
Supplemental content

IMPORTANCE Cancers of the upper gastrointestinal tract remain a major contributor to the global cancer burden. The accurate mapping of tumor margins is of particular importance for curative cancer resection and improvement in overall survival. Current map preclude a full resection margin assessment in real time.

OBJECTIVE To evaluate whether diffuse reflectance spectroscopy (DRS) on esophageal cancer specimens can differentiate tissue types and provide re to the operator.

DESIGN, SETTING, AND PARTICIPANTS This was a prospective ex vivo validat undergoing esophageal or gastric cancer resection were prospectively recr study between July 2020 and July 2021 at Hammersmith Hospital in Lond Kingdom. Tissue specimens were included for patients undergoing elective

Figure 1. Diffuse Reflectance Spectroscopy (DRS) Instrumentation for Ex Vivo Data Acquisition



The DRS probe was connected to both the light source (HL-2000-HP; Ocean Optics) and the spectrometer (USB4000; Ocean Optics) to allow for data acquisition and sample illumination. All electronic devices communicated with proprietary software designed with Python version 3.6 (Python Software Foundation) on the laptop.[32] VNIR indicates visible and near-infrared.

nature medicine

REVIEW ARTICLE

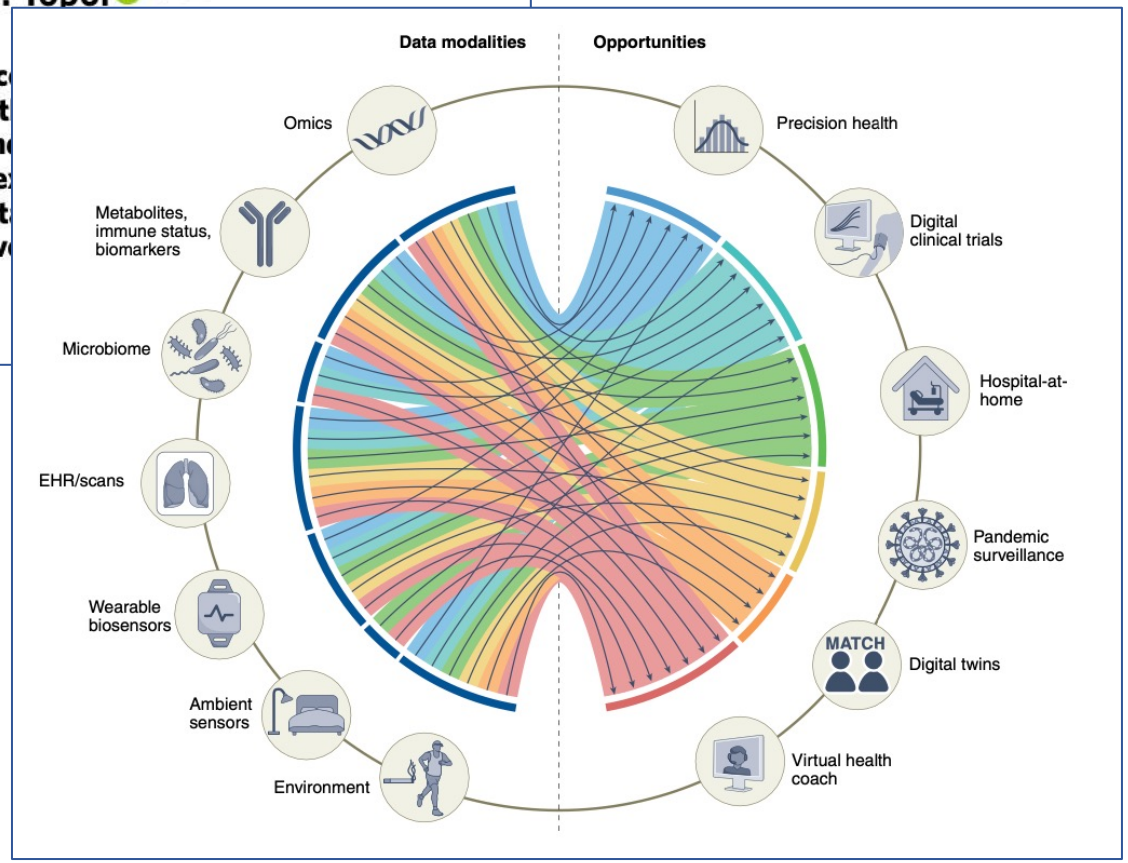
https://doi.org/10.1038/s41591-022-01981-2

Check for updates

Multimodal biomedical AI

Julián N. Acosta[1], Guido J. Falcone[1], Pranav Rajpurkar[2,4] ✉ and Eric J. Topol[3,4] ✉

**The increasing availability of biomedical data from large biobanks, electronic health rec
ambient biosensors, and the lower cost of genome and microbiome sequencing have set t
timodal artificial intelligence solutions that capture the complexity of human health an
the key applications enabled, along with the technical and analytical challenges. We e
medicine, digital clinical trials, remote monitoring and care, pandemic surveillance, digit
assistants. Further, we survey the data, modeling and privacy challenges that must be ov
multimodal artificial intelligence in health.**



Oncology

EDITORIAL

The role of aging in cancer

Aaron Havas, Shanshan Yin and P. D. Adams

Sanford Burnham Prebys Medical Discovery Institute, La Jolla, CA, USA

Many cancers show a striking increase in incidence with age, and age is the biggest single risk factor for many cancers. Moreover, pro-longevity interventions that extend lifespan also tend to suppress the incidence of cancer, underscoring the tight relationship between aging and cancer [1]. However, the molecular basis of this relationship, and why the incidence of cancer increases with age, is poorly understood.

1. Cancer in the elderly is not simply a reflection of the time taken to accumulate oncogenic mutations

Genetic mutations are critical drivers of most cancers

genetic alterations. Although this model was transformative for conceptualizing the origins and progression of CRC and then other cancers, the Vogelgram is primarily a model of histological progression, not time-dependent progression. Indeed, it has been estimated by Vogelstein and coworkers that the entire progression from normal intestinal epithelium to CRC takes approximately 28 years [17]. CRC has an average age of diagnosis at 68 or 72 years (men and women, respectively; www.cancer.org), so the Vogelgram does not adequately explain the age dependence of CRC. More recent models have proposed a punctuated model of cancer evolution, whereby one or a few genetic catastrophes, encompassing many simultaneous

CANCER GENETICS

commentaries

Universal Germline Genetic Testing for Hereditary Cancer Syndromes in Patients With Solid Tumor Cancer

Edward D. Esplin, MD, PhD[1]; Sarah M. Nielsen, MS[1]; Sara L. Bristow, PhD[1]; Judy E. Garber, MD, MPH[2]; Heather Hampel, MS[3]; Huma Q. Rana, MD, MPH[2]; N. Jewel Samadder, MD[4,5,6]; Neal D. Shore, MD, FACS[7]; and Robert L. Nussbaum, MD[1]

JCO Precis Oncol 6:e2100516. © 2022 by American Society of Clinical Oncology

Historically, professional society guidelines have recommended limited genetic testing for hereditary cancer syndromes (HCS) to patients with cancer thought to be at highest risk for carrying pathogenic/likely pathogenic germline variants (PGVs) in a few health insurance payers specifying which patients are eligible for testing reimbursement *and* which genes should be included in testing. For example, both private payers and Medicare reference the National Comprehensive Cancer Network (NCCN)

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www.nature.com/modpathol

ARTICLE OPEN

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Direct identification of *ALK* and *ROS1* fusions in non-small cell lung cancer from hematoxylin and eosin-stained slides using deep learning algorithms

Chen Mayer[1,4✉], Efrat Ofek[1,4], Danielle Even Fridrich[1], Yossef Molchanov[1], Rinat Yacobi[1], Inbal Gazy[2], Ido Hayun[2], Jonathan Zalach[2], Nurit Paz-Yaacov[2] and Iris Barshack[1,3]

Anaplastic lymphoma kinase (*ALK*) and ROS oncogene 1 (*ROS1*) gene fusions are well-established key players in non-small cell lung cancer (NSCLC). Although their frequency is relatively low, their detection is important for patient care and guides therapeutic decisions. The accepted methods used for their detection are immunohistochemistry (IHC) and fluorescence in situ hybridization (FISH) ass

Table 1. Summary of *ALK/ROS1* classifier results.

		Conventional methods		AI-based model						
	N	# Positive	# Negative	TP	TN	FP	FN	Sensitivity	Specificity	Concordance
ALK	72	6	66	6	66	0	0	100%	100%	100%
ROS1	68	2	66	2	65	1	0	100%	98.48%	98.53%

TP true positive, *TN* true negative, *FP* false positive, *FN* false negative.

nature communications

Article

https://doi.org/10.1038/s41467-022-33026-0

Integrating and formatting biomedical data as pre-calculated knowledge graph embeddings in the Bioteque

Received: 6 May 2022

Accepted: 30 August 2022

Published online: 09 September 2022

Check for updates

Adrià Fernández-Torras[1], Miquel Duran-Frigola[1,2], Martino Bertoni[1], Martina Locatelli[1] & Patrick Aloy[1,3]

Biomedical data is accumulating at a fast pace and integrating it into a framework is a major challenge, so that multiple views of a given biol event can be considered simultaneously. Here we present the Bioteq resource of unprecedented size and scope that contains pre-calculate

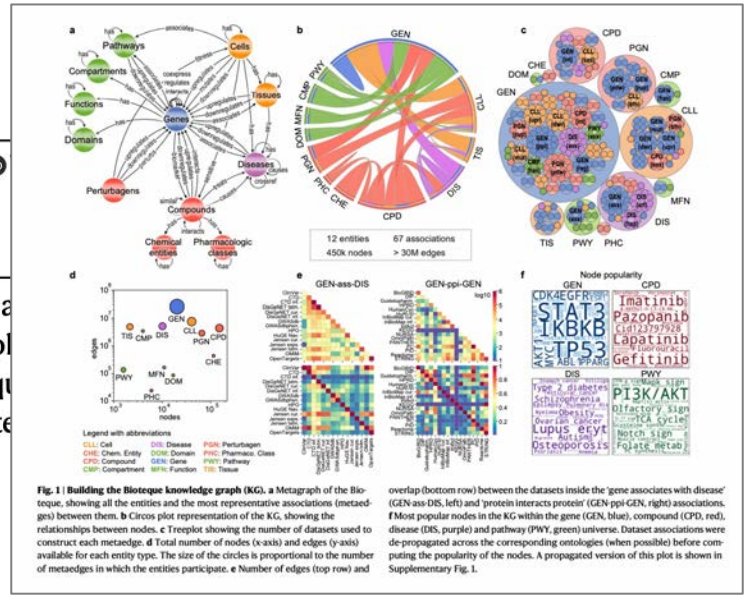

Fig. 1 | Building the Bioteque knowledge graph (KG). **a** Metagraph of the Bioteque, showing all the entities and the most representative associations (metaedges) between them. **b** Circos plot representation of the KG, showing the relationships between nodes. **c** Treeplot showing the number of datasets used to construct each metaedge. **d** Total number of nodes (x-axis) and edges (y-axis) available for each entity type. The size of the circles is proportional to the number of metaedges in which the entities participate. **e** Number of edges (top row) and overlap (bottom row) between the datasets inside the 'gene associates with disease' (GEN ass-DIS, left) and 'protein interacts protein' (GEN ppi-GEN, right) associations. **f** Most popular nodes in the KG within the gene (GEN, blue), compound (CPD, red), disease (DIS, purple) and pathway (PWY, green) universe. Dataset associations were de-propagated across the corresponding ontologies (when possible) before computing the popularity of the nodes. A propagated version of this plot is shown in Supplementary Fig. 1.

https://bioteque.irbbarcelona.org/

nature biomedical engineering

ARTICLES

https://doi.org/10.1038/s41551-022-00936-9

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OPEN

Expert-level detection of pathologies from unannotated chest X-ray images via self-supervised learning

Ekin Tiu[1,2,4], Ellie Talius[1,2,4], Pujan Patel[1,2,4], Curtis P. Langlotz[3], Andrew Y. Ng[1] and Pranav Rajpurkar[2]

In tasks involving the interpretation of medical images, suitably traine mance of medical experts. Yet such a high-level of performance typica datasets that have been painstakingly annotated by experts. Here we sh images that lack explicit annotations performs pathology-classification gists. On an external validation dataset of chest X-rays, the self-supervis detection of three pathologies (out of eight), and the performance genera for model training, to multiple image-interpretation tasks and to dataset

Deep learning has enabled the automation of complex medical image interpretation tasks, such as disease diagnosis, form of contrast

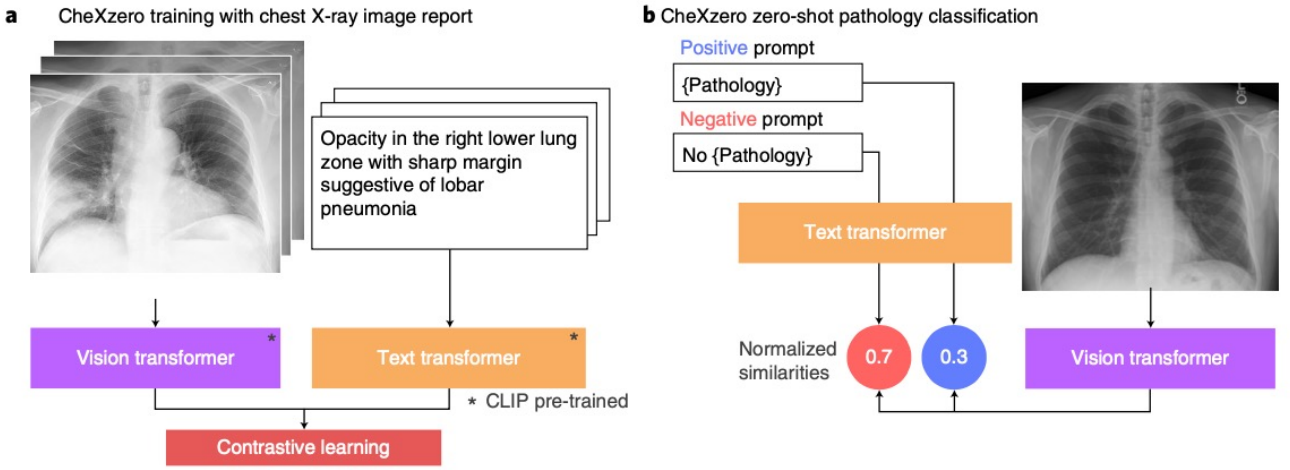

Fig. 1 | The self-supervised model classifies pathologies without training on any labelled samples. a, Training pipeline. The model learns features from raw radiology reports, which act as a natural source of supervision. **b**, Prediction of pathologies in a chest X-ray image. For each pathology, we generated a positive and negative prompt (such as 'consolidation' versus 'no consolidation'). By comparing the model output for the positive and negative prompts, the self-supervised method computes a probability score for the pathology, and this can be used to classify its presence in the chest X-ray image.

Review

Exploring tissue architecture using spatial transcriptomics

https://doi.org/10.1038/s41586-021-03634-9

Received: 3 February 2021

Accepted: 11 May 2021

Published online: 11 August 2021

Check for updates

Anjali Rao[1,3], Dalia Barkley[1,3], Gustavo S. França[1] & Itai Yanai[1,2]✉

Deciphering the principles and mechanisms by which gene activity orchestrates complex cellular arrangements in multicellular organisms has far-reaching implications for research
next-generation sequenc
power of spatial transcrip
systematically throughou
insights in neuroscience

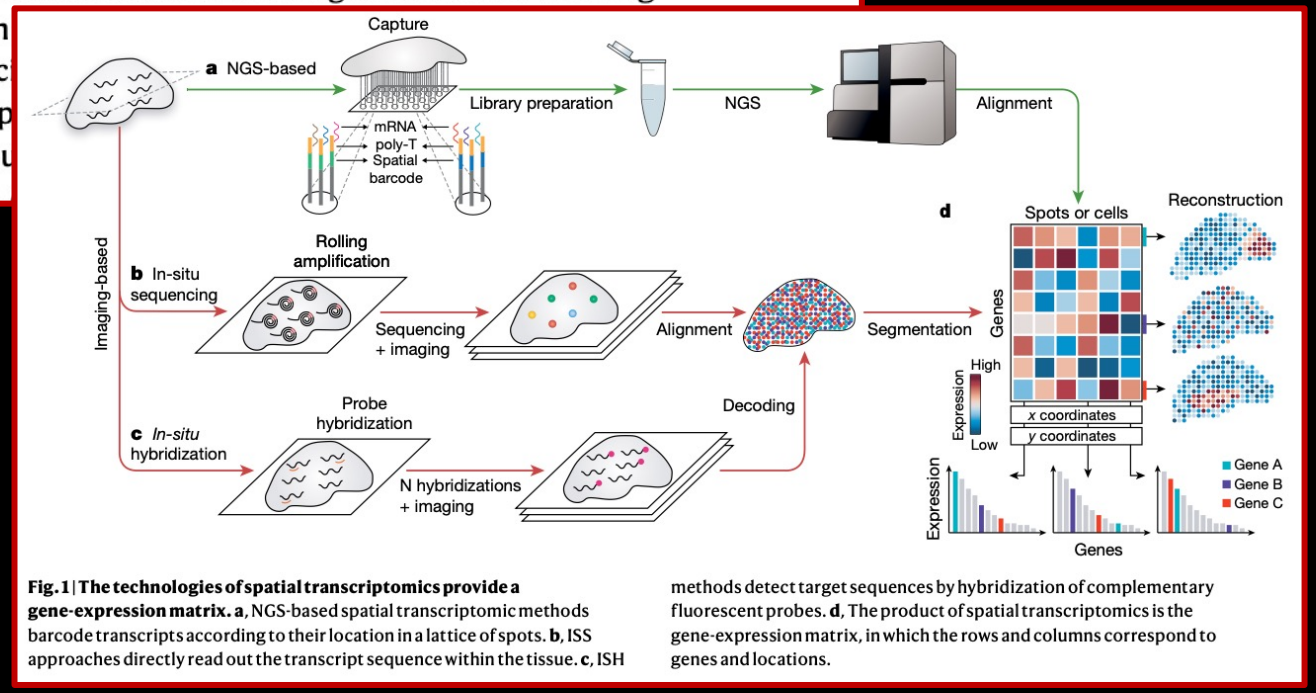

Fig. 1 | The technologies of spatial transcriptomics provide a gene-expression matrix. a, NGS-based spatial transcriptomic methods barcode transcripts according to their location in a lattice of spots. **b**, ISS approaches directly read out the transcript sequence within the tissue. **c**, ISH methods detect target sequences by hybridization of complementary fluorescent probes. **d**, The product of spatial transcriptomics is the gene-expression matrix, in which the rows and columns correspond to genes and locations.

Article

A cellular hierarchy in melanoma uncouples growth and metastasis

https://doi.org/10.1038/s41586-022-05242-7

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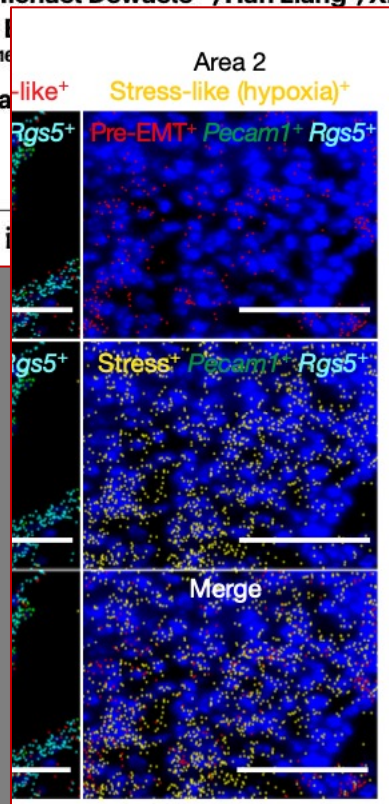
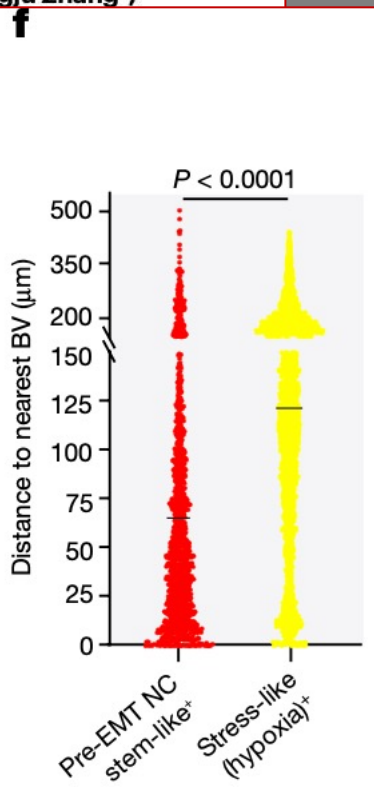
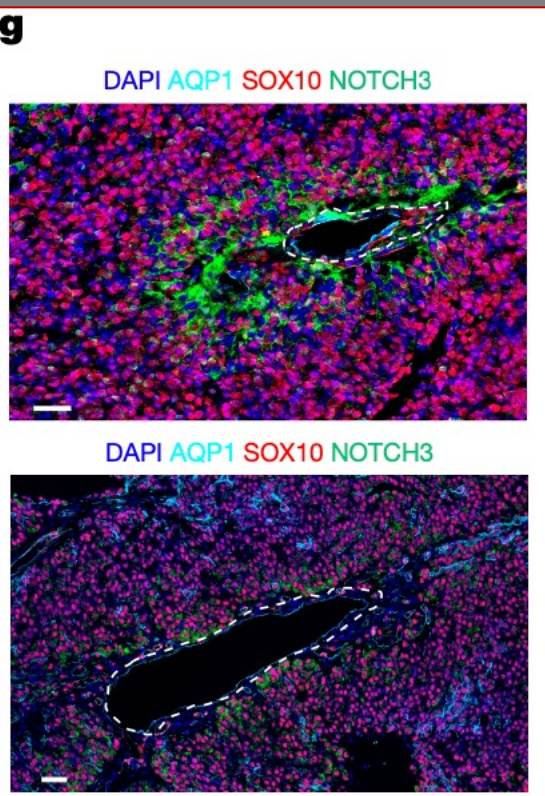
Check for updates

Panagiotis Karras[1,2], Ignacio Bordeu[3,4,22,26], Joanna Pozniak[1,2,26], Ada Nowosad[1,2,26], Cecilia Pazzi[1,2], Nina Van Raemdonck[1,2], Ewout Landeloos[1,2], Yannick Van Herck[5], Dennis Pedri[1,2], Greet Bervoets[1,2], Samira Makhzami[1,2], Jia Hui Khoo[6], Benjamin Pavie[7,8,9], Jochen Lamote[10], Oskar Marin-Bejar[1,2], Michael Dewaele[1,2], Han Liang[6], Xingju Zhang[6], Yichao Hua[2,11], Jasper Wouters[12,13], Robin [illegible], Francesca Bosisio[16], Joost van den Oord[16], Oliver Bechter[5], Cedric Blanpain[20], Benja[illegible], Jean-Christophe Marine[1,2]✉

Although melanoma is notorious for i[illegible]





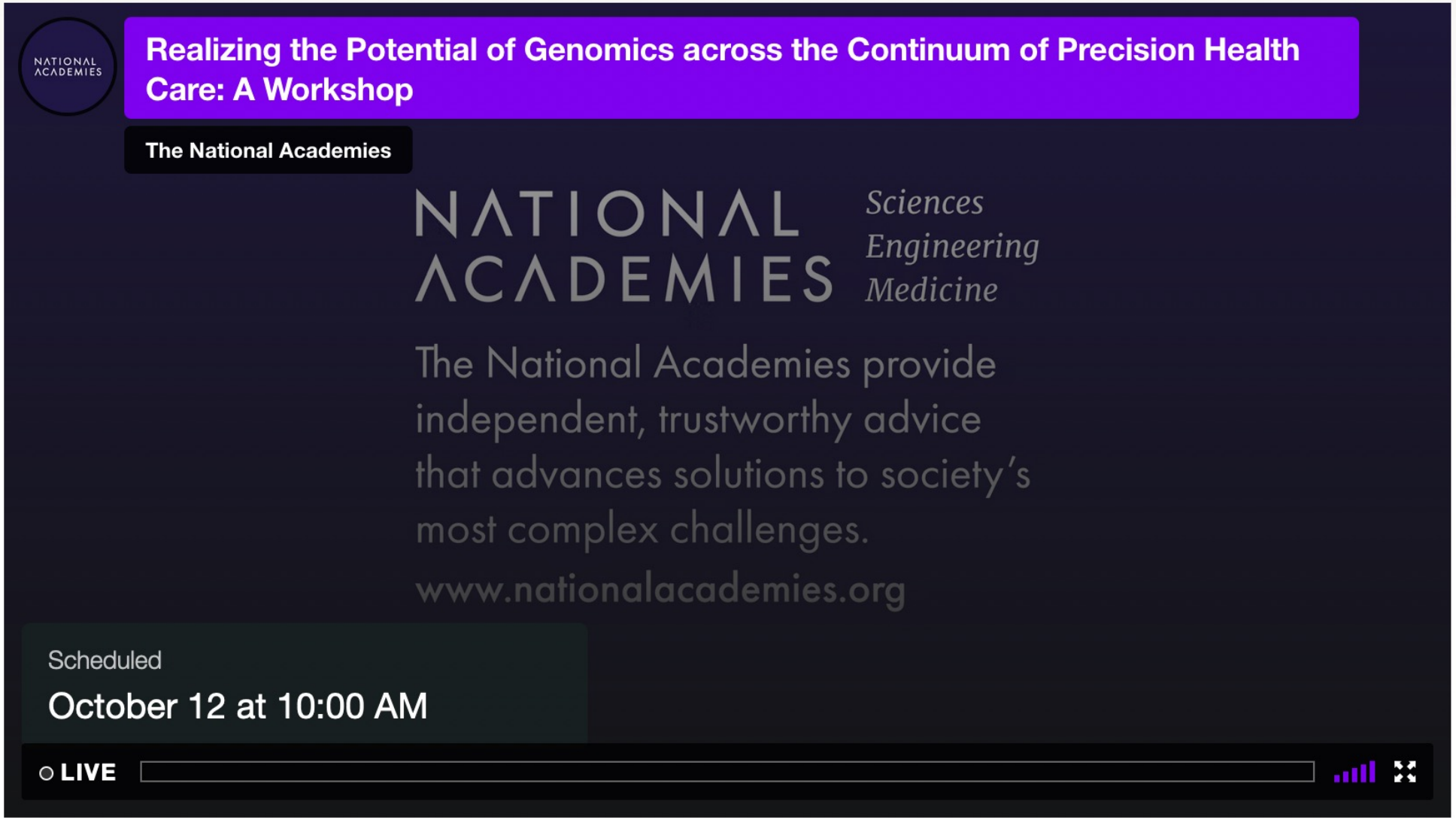


Events

Roundtable on Genomics and Precision Health

This roundtable from the Health and Medicine Division brings together diverse voices to encourage innovation and actions that foster the wide adoption of and equitable access to the benefits of genomics and precision health.

Webcast


Realizing the Potential of Genomics across the Continuum of Precision Health Care: A Workshop
The National Academies
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Sciences
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Medicine
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www.nationalacademies.org
Scheduled
October 12 at 10:00 AM
LIVE

Realizing the Potential of Genomics across the Continuum of Precision Health Care: A Workshop

- https://www.nationalacademies.org/event/10-12-2022/realizing-the-potential-of-genomics-across-the-continuum-of-precision-health-care-a-workshop

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Please note that oral and poster submission for #PathVisions22 is now closed.