Monthly Steering Committee Meetings

July 27 2022 3-4PM ET

Pathology Innovation Collaborative Community

Advancing Telehealth Beyond COVID–19 Act of 2022

- Removing geographic requirements
  - Clear indication and alleviates national concerns
  - Is expected to pass the house and will result in a 2-year extension
- Devices + diagnostics is not mentioned (remains TBD)

JULY 22, 2022

RULES COMMITTEE PRINT 117–59

TEXT OF H.R. 4040, THE ADVANCING TELEHEALTH BEYOND COVID–19 ACT OF 2021

[Showing the text of H.R. 4040, as introduced, with modifications.]

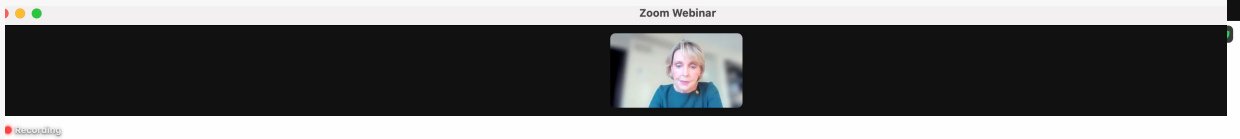
SECTION 1. SHORT TITLE.

This Act may be cited as the "Advancing Telehealth Beyond COVID–19 Act of 2022".

SEC. 2. REMOVING GEOGRAPHIC REQUIREMENTS AND EXPANDING ORIGINATING SITES FOR TELEHEALTH SERVICES.

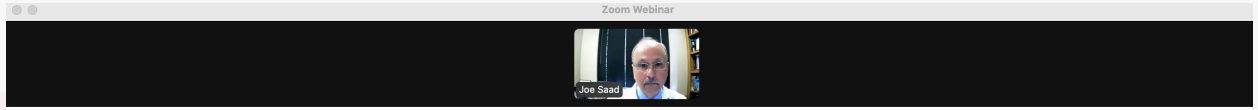
MDUFA/VALID

CAP Update of LDTs and the VALID Act



Update on the VALID Act

- Senate HELP Committee released a draft of the VALID Act on May 17.
  - VALID Act included in FDA user fee reauthorization bill that must pass by September 30.
  - The bill would establish a comprehensive regulatory framework for clinical laboratory tests that includes laboratory-developed tests (LDTs).
  - The CAP submitted comments on the bill on May 22.
  - HELP Committee marked up the bill on June 14.
- The CAP supports many provisions in the bill because several are simi to policies advocated for by the CAP since 2009.
- VALID Act is a viable bill.
  - It has bipartisan, bicameral support.
  - It is the product of a four-year multistakeholder process.
  - The CAP expects some version of the bill will be eventually enacted.



Stay Informed Through the CAP

- Follow CAP on social media
  - Twitter @CAPDCAdvocacy
  - Facebook.com/capathologists
- Visit CAP.org > advocacy
- Read *Advocacy Update*
- Join PathNET, the CAP's grassroots advocacy network

Senator Burr press release

The politics of passing a major FDA funding bill just got complicated

statnews.com/2022/07/19/politics-passing-major-fda-funding-bill-complicated

July 19, 2022

What happened?

Burr, the top Republican on the Senate committee tasked with reauthorizing user fees, basically threw down the gauntlet on Thursday when he introduced a so-called "clean" user fee bill without any of the extra FDA-related policies that senators had agreed to tack on.

Burr implied in the press release that the earlier, more complicated legislation no longer had enough support to pass the full Senate because "anti-innovation policies were attached to the bill in committee."

Letters to Congress on VALID

AMP, AACC, ASCP, API & many more

July 6, 2022

The Honorable Chuck Schumer
Majority Leader
United States Senate
322 Hart Senate Office Building
Washington, DC 20510

The Honorable Mitch McConnell
Minority Leader
United States Senate
317 Russell Senate Office Building
Washington, DC 20510

The Honorable Nancy Pelosi
Speaker
U.S. House of Representatives
1236 Longworth House Office Building
Washington, DC 20515

The Honorable Kevin McCarthy
Minority Leader
U.S. House of Representatives
2468 Rayburn House Office Building
Washington, DC 20515

Dear Majority Leader Schumer, Minority Leader McConnell, Speaker Pelosi, and Minority Leader McCarthy,

We write to you today to express our significant concerns with the Verifying Accurate Leading-edge IVCT Development (VALID) Act of 2022 and request that you provide additional and sufficient time to resolve these concerns prior to advancing this legislation as part of the Food and Drug Administration Safety and Landmark Advancements (FDASLA) Act. The undersigned organizations represent a diverse and broad community of healthcare professionals, patient advocates, industry organizations, medical institutions, and pathology departments who practice laboratory medicine, provide clinical testing services, and deliver high quality care to patients throughout the US.

CAP, ASCO, FOCR, Pew, Roche & many more

July 20, 2022

The Honorable Frank Pallone, Jr.
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Cathy McMorris Rodgers
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Patty Murray
Chair
Committee on Health, Education,
Labor and Pensions
United States Senate
428 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Richard Burr
Ranking Member
Committee on Health, Education,
Labor and Pensions
United States Senate
833 Hart Senate Office Building
Washington, D.C. 20510

Dear Chairman Pallone, Chair Murray, and Ranking Members Rodgers and Burr:

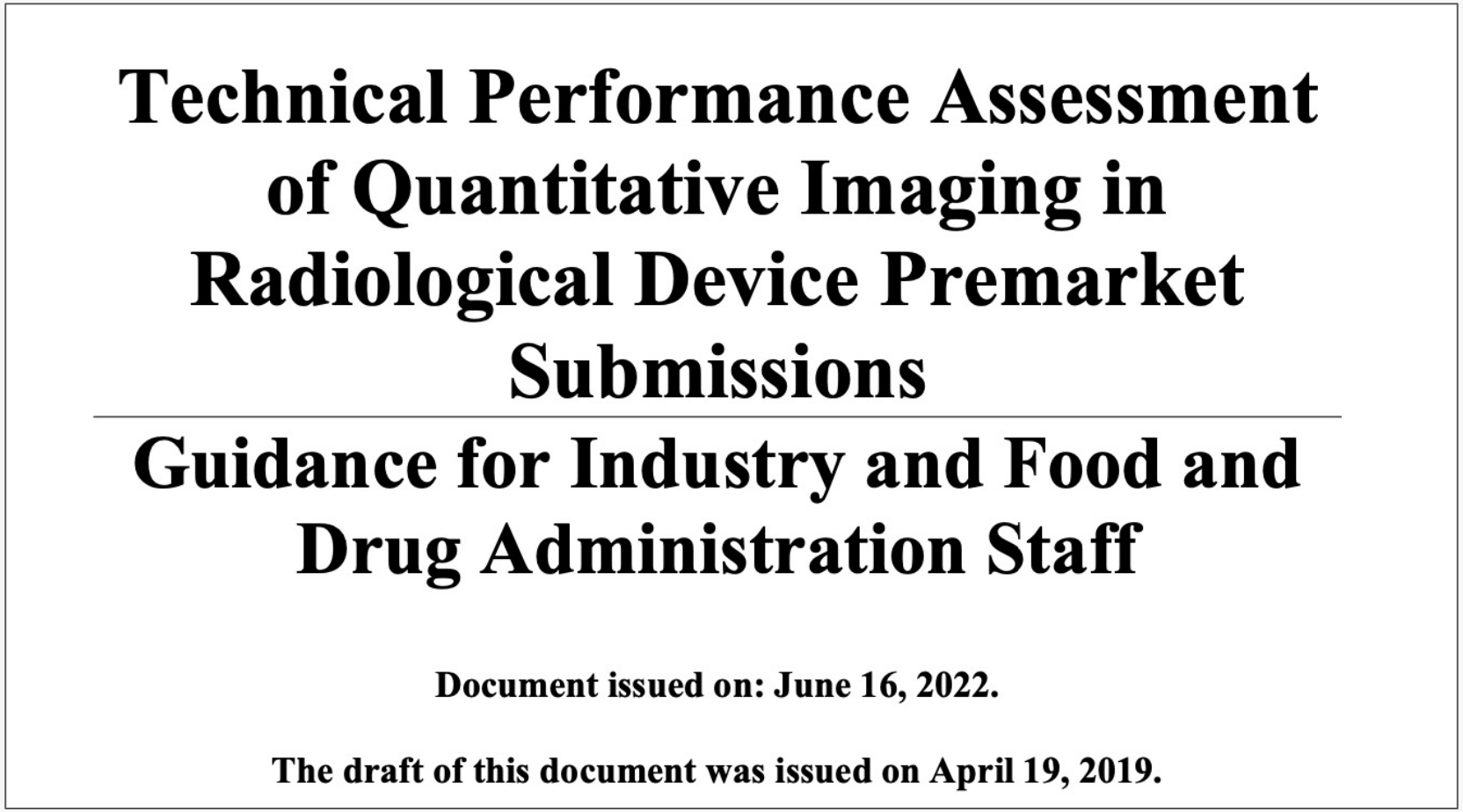
We write on behalf of a diverse group of stakeholders, representing test manufacturers, laboratories, physicians, healthcare providers, patients, consumers, and public health groups, and we are united in a commitment to ensuring patients' access to accurate and reliable *in vitro* diagnostics. We appreciate your continuing efforts to deliver vital funding to the U.S. Food and Drug Administration (FDA), and we ask that as you reconcile differences between the user fee reauthorization legislation passed by the House Committee on Energy and Commerce and the Senate Committee on Health, Education, Labor and Pensions (HELP), you address an urgent public health issue by enacting the diagnostics reform provisions included in the Food and Drug Administration Safety and Landmark Advancements (FDASLA) Act of 2022 (S. 4348).

Plcc Charter

- We have received questions about how to join
- Free, available, charter can be signed → symbol on the landing page and participation
- Non-profits 501(c)(3) can join
- Proposal to start a non-profit organization as a facilitator

FDA Corner

FDA Corner



Technical Performance Assessment of Quantitative Imaging in Radiological Device Premarket Submissions

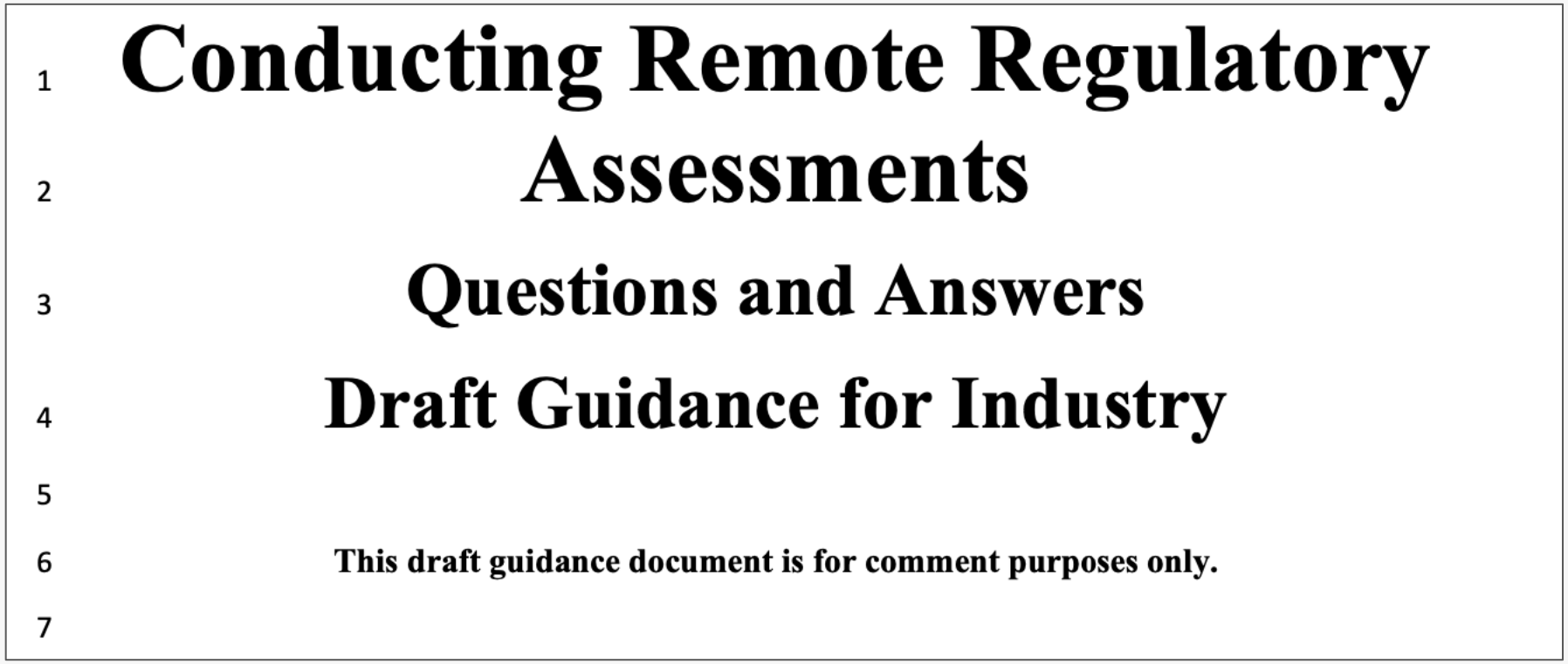
---

Guidance for Industry and Food and Drug Administration Staff

Document issued on: June 16, 2022.

The draft of this document was issued on April 19, 2019.

FDA Corner



Conducting Remote Regulatory Assessments

Questions and Answers

Draft Guidance for Industry

This draft guidance document is for comment purposes only.

- FDA details optimized approach for regulatory oversight tools to better protect public health

FDA Corner

- FDA's Ongoing Use of Inspectional Tools for Ensuring Access to Safe, Quality Food and Medical Products During the COVID-19 Pandemic
- Catalog of regulatory science tools

FDA Corner

FDA investigating possible increased risk of death with lymphoma medicine Ukoniq (umbralisib)

FDA Corner

eMDR System Enhancements

Share Tweet Linkedin Email Print

This page lists enhancements to CDRH's Electronic Medical Device Reporting (eMDR) system. The FDA eSubmitter client is updated concurrently with the eMDR system, but industry with system-to-system, or AS2, accounts with the FDA Electronic Submissions Gateway (ESG), should use the information on this page to plan with these eMDR system enhancements as soon as possible.

The FDA recognizes the importance of providing early notice ar potential eMDR system changes, especially for manufacturers s reports via AS2. Therefore, the FDA is adopting a yearly schedu implementing enhancements to the eMDR System.

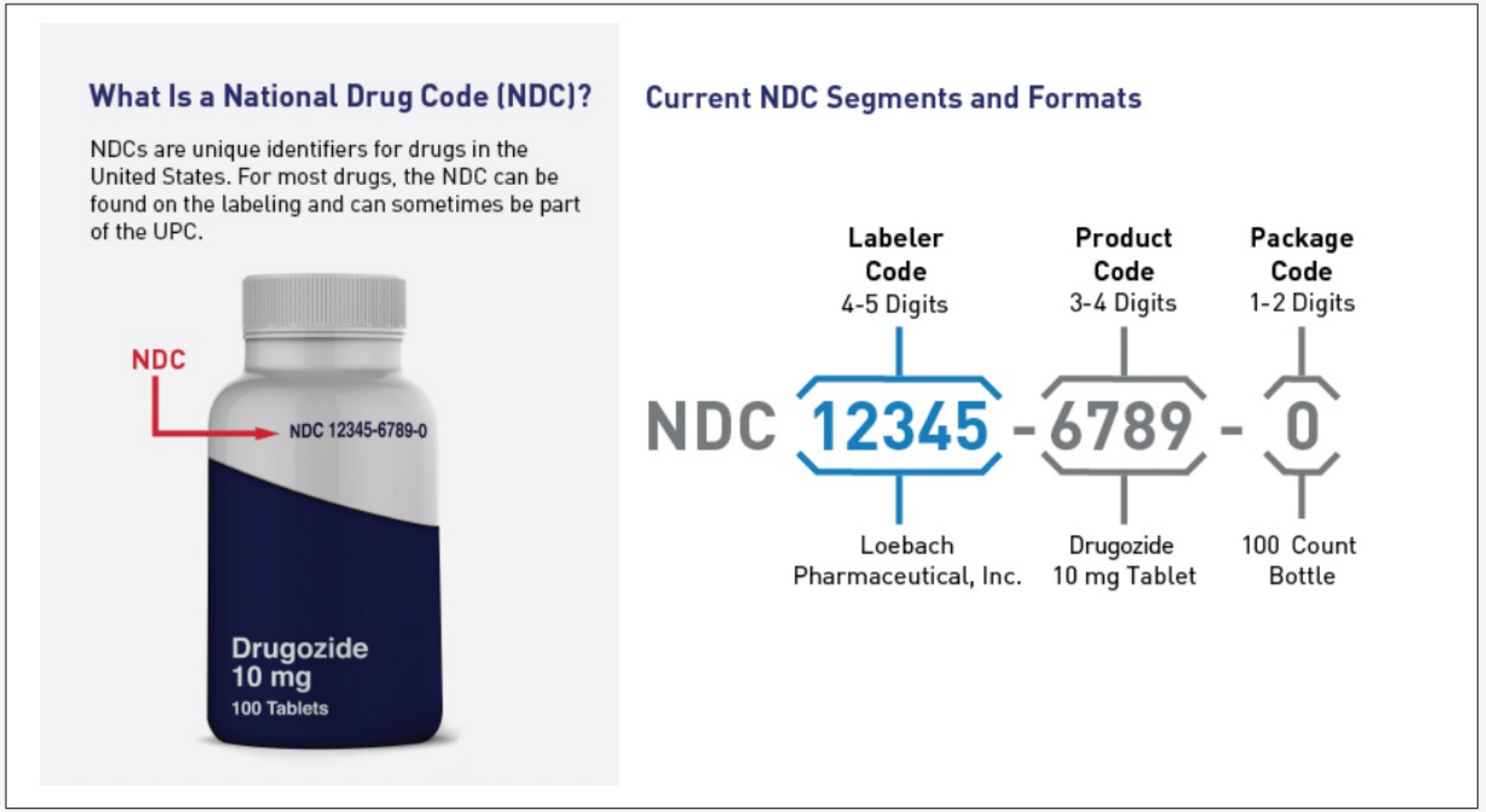
Coding Resources for Medical Device Reports

Share Tweet Linkedin Email Print

This page contains a comprehensive set of resources for reporters to use when selecting event codes in a Medical Device Report (MDR) and contains information about the codes and the MedWatch Medical Device Reporting Code Instructions, sometimes referred to as the coding manual.

FDA Corner

- Proposed rule on revising the national drug code format

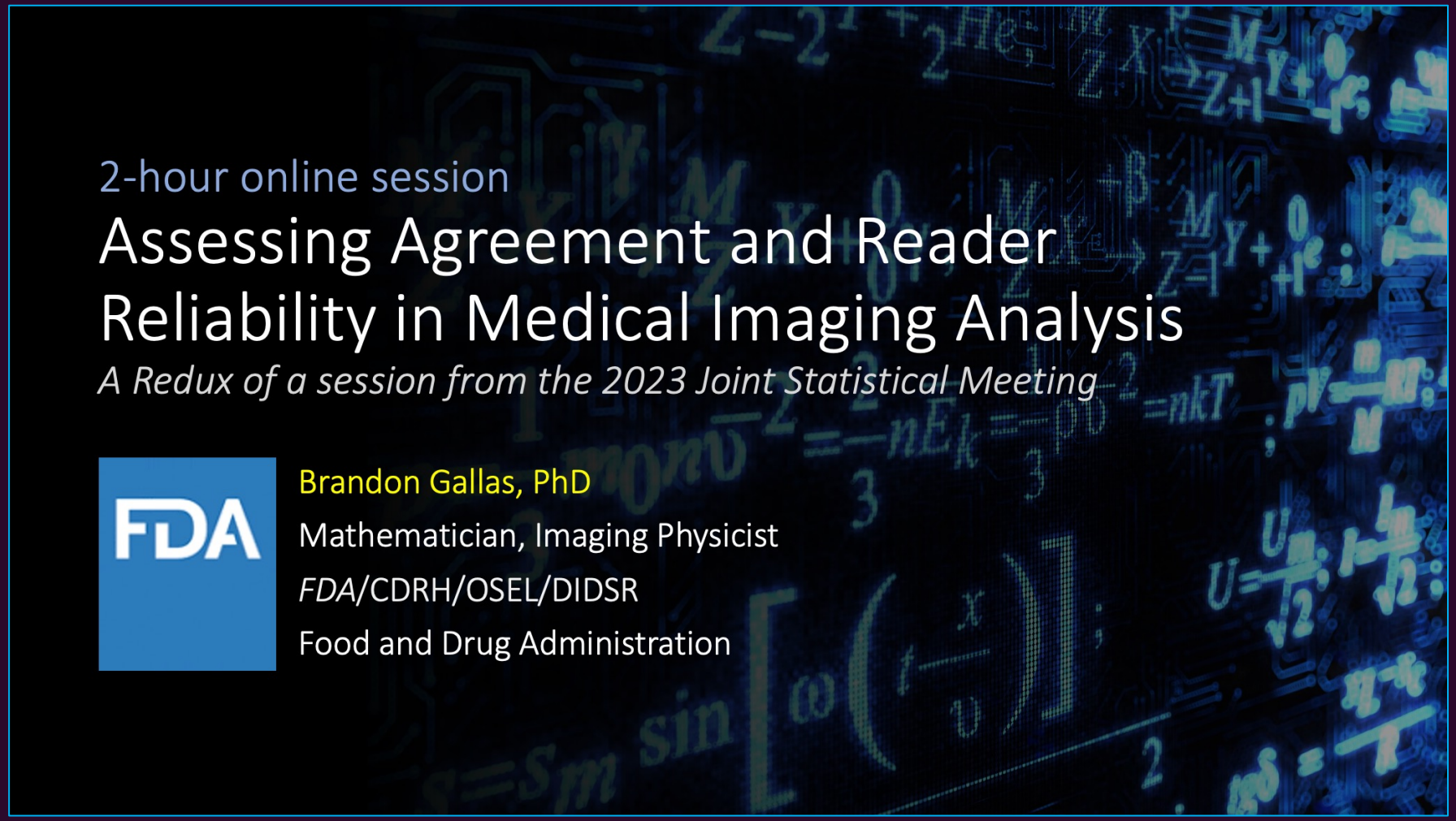


Upcoming presentation

August 5, 2022 at 12:00-1:00 PM Eastern Time

Upcoming presentation

Date TBD



News & Updates

Workgroup Update

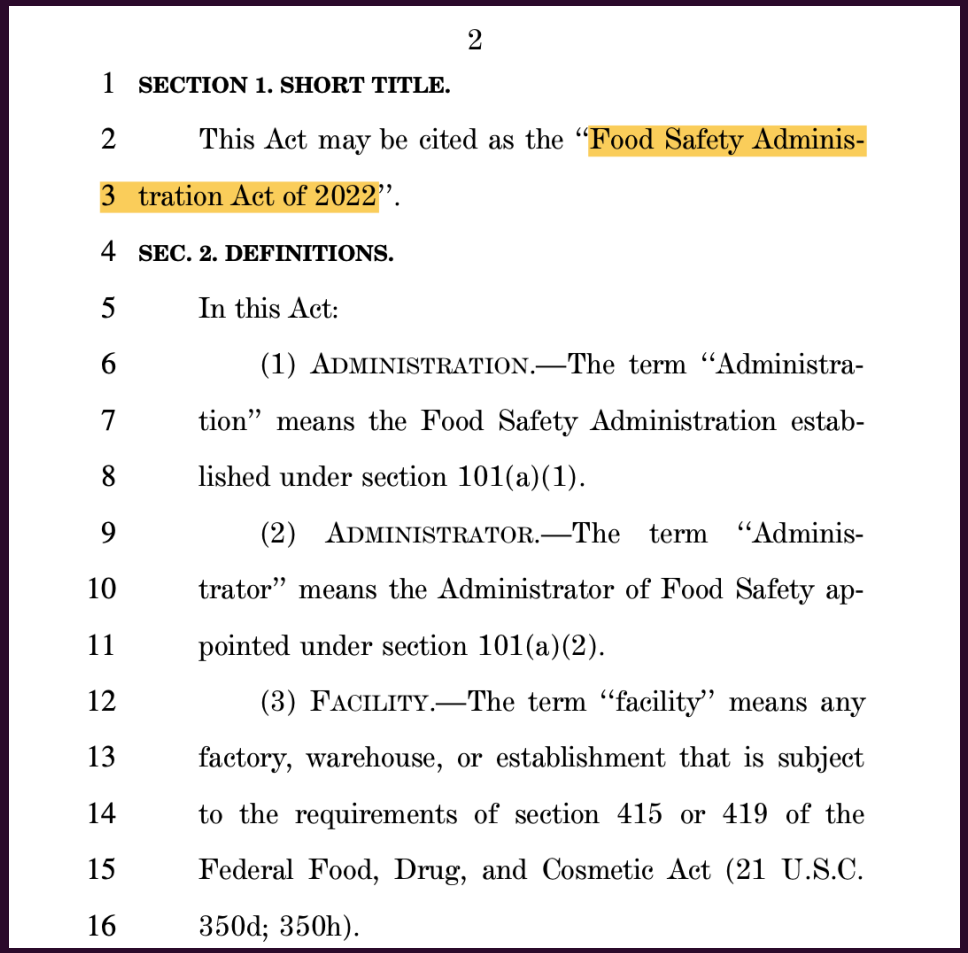
- Truthing & Validation working group

Updates

July 2022

- **Info Sharing**: One day, the public health emergency will be declared over. Here is guidance on what happens to devices that fall within pandemic enforcement policies, like WSI scanners: LINK
- Open-Position: ORISE Fellow
  - Victor Garcia, MD, is transitioning into an FDA/CDRH/DIDSR full-time staff fellow
  - We therefore have an open ORISE Fellow position for the next year (starting 01 October 2022): Statistics and Informatics Support the Assessment of Artificial Intelligence and Machine Learning
- Actively recruiting now – please distribute! jobDescriptionDigitalPathologyAIML-20220617-2_1.pdf (106 KB, uploaded by Katherine N Elfer 5 days ago)
- **Needed:** We are looking for an FDA-cleared Scanner. We are targeting the the Aperio AT2 DX because it has a format that is open enough to be supported by several software tools and platforms.
  - One batch of pivotal study slides are in our hands!

Update: Food Safety Administration Act of 2022



2

SECTION 1. SHORT TITLE.

This Act may be cited as the "Food Safety Administration Act of 2022".

SEC. 2. DEFINITIONS.

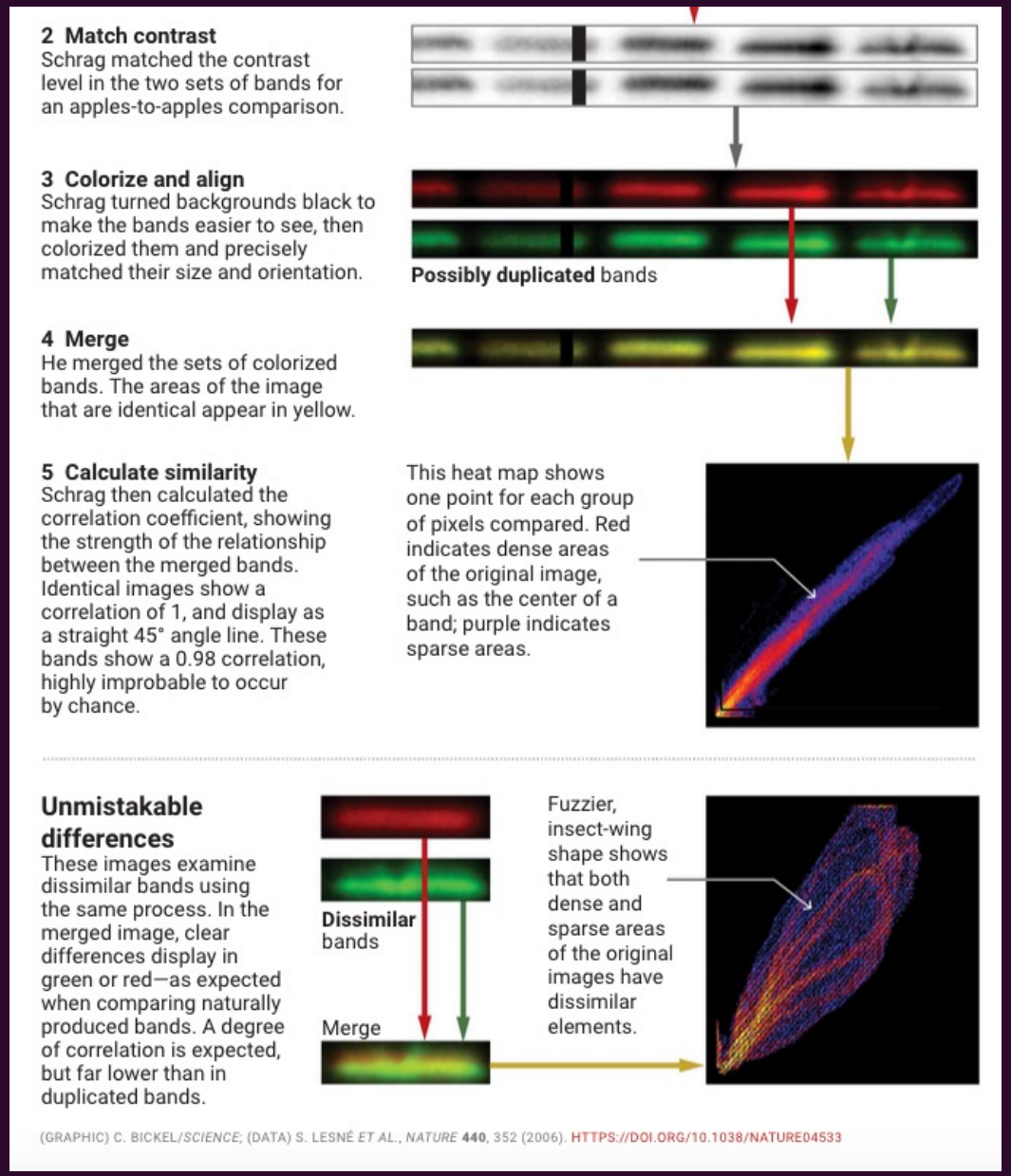
In this Act:

(1) ADMINISTRATION.—The term "Administration" means the Food Safety Administration established under section 101(a)(1).

(2) ADMINISTRATOR.—The term "Administrator" means the Administrator of Food Safety appointed under section 101(a)(2).

(3) FACILITY.—The term "facility" means any factory, warehouse, or establishment that is subject to the requirements of section 415 or 419 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d; 350h).

- Baby formula supply shortage
- Proposes to separate "food" oversight from the FDA
- New enforcement entity would be a separate branch under HHS
- Relevance: drug development relies on intra-agency experience



Dispute about data portrayal in Alzheimer's disease articles

- Image-based assessment of data similarity / dissimilarity
- Regulatory relevance related to disease mechanisms and drug development

AI advancements in Sepsis diagnostics

AI SPEEDS SEPSIS DETECTION TO PREVENT HUNDREDS OF DEATHS

The new system identifies patients at risk for the illness, which is notoriously difficult to detect and develops quickly

Article | Published: 21 July 2022

Factors driving provider adoption of the TREWS machine learning-based early warning system and its effects on sepsis treatment timing

Katharine E. Henry, Roy Adams, Cassandra Parent, Hossein Soleimani, Anirudh Sridharan, Lauren Johnson, David N. Hager, Sara E. Cosgrove, Andrew Markowski, Eili Y. Klein, Edward S. Chen, Mustapha O. Saheed, Maureen Henley, Sheila Miranda, Katrina Houston, Robert C. Linton II, Anushree R. Ahluwalia, Albert W. Wu & Suchi Saria

Nature Medicine **28**, 1447–1454 (2022) | Cite this article

961 Accesses | **3** Citations | **123** Altmetric | Metrics

- AI speeds sepsis detection to prevent hundreds of deaths
- Evaluation of a Multivalent Transcriptomic Metric for Diagnosing Surgical Sepsis and Estimating Mortality Among Critically Ill Patients

Resources

Guidance on Qualification and Classification of Software in Regulation (EU)

resources

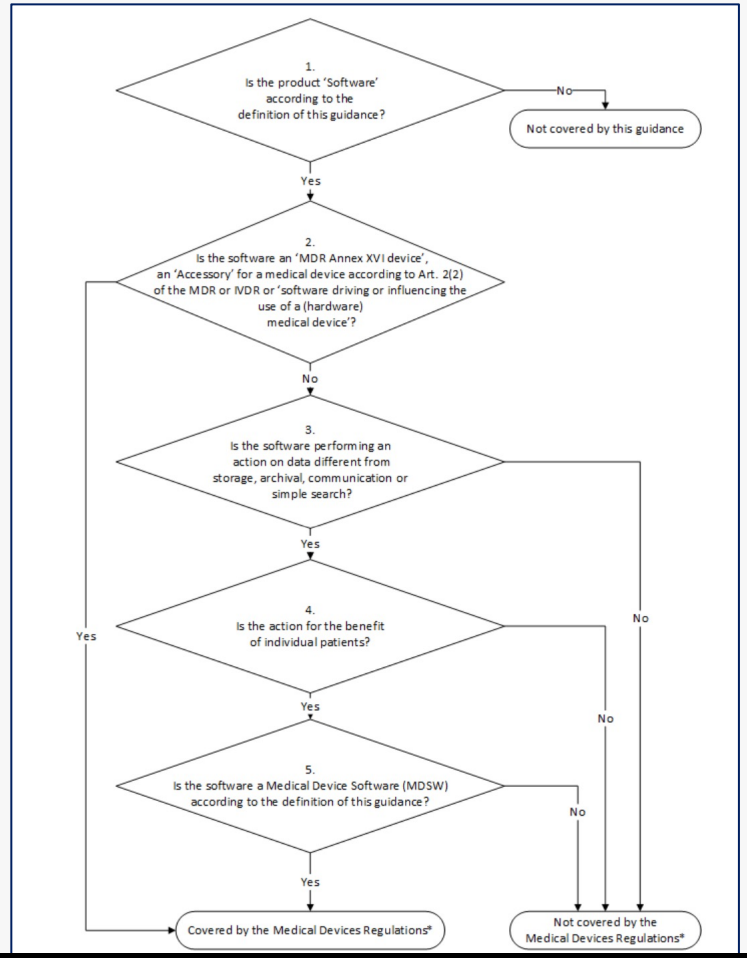
Medical Device

Medical Device Coordination Group Document MDCG 2019-11

MDCG 2019-11

Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR

October 2019



Machine Learning-enable medical devices: Key Terms and Definitions

resources

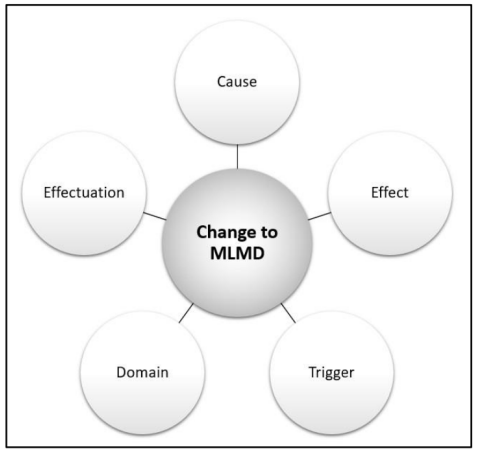


Figure 2 Aspects of MLMD Changes

The **cause** refers to the source of the change to the MLMD, for example, re-training with new or appended data different training methods or ML training algorithms, additional ML model, tuning, etc.

The **effect** refers to the resulting change to the MLMD, which can include amended intended use/indications for use; modified performance, changes in inputs, outputs, etc.

The **trigger** refers to the event that prompts or instigates the change to the MLMD, which can include performance thresholds, training data batch-size thresholds, exposure to new data/experiences, scheduled time intervals, MLMD environmental changes, user feedback, etc.

The **domain** refers to the scope or applicable extent of the change to the MLMD, which can be categorized as either homogeneous or heterogeneous. A homogeneous change is a uniform change that occurs universally (sometimes referred to as a global adaptation, note that global does not denote around-the-world). Heterogeneous changes are non-uniform changes that can be specific to one clinic, region, demographic, etc. (sometimes referred to as local adaptations)[4].

The **effectuation** refers to where the mechanism for change implementation resides

IMDRF International Medical Device Regulators Forum

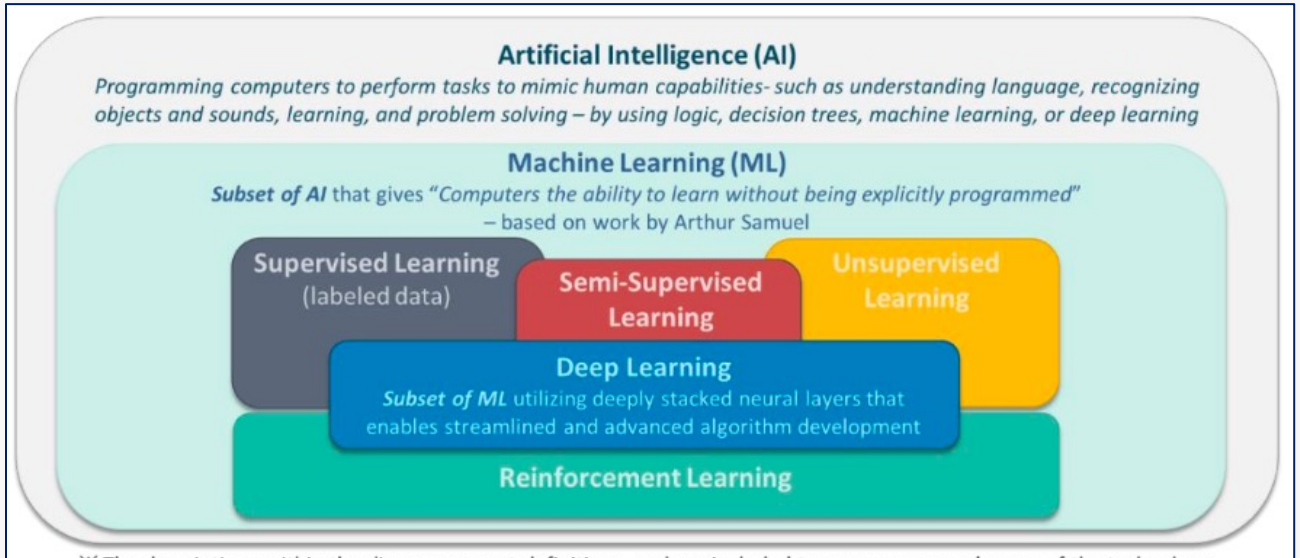
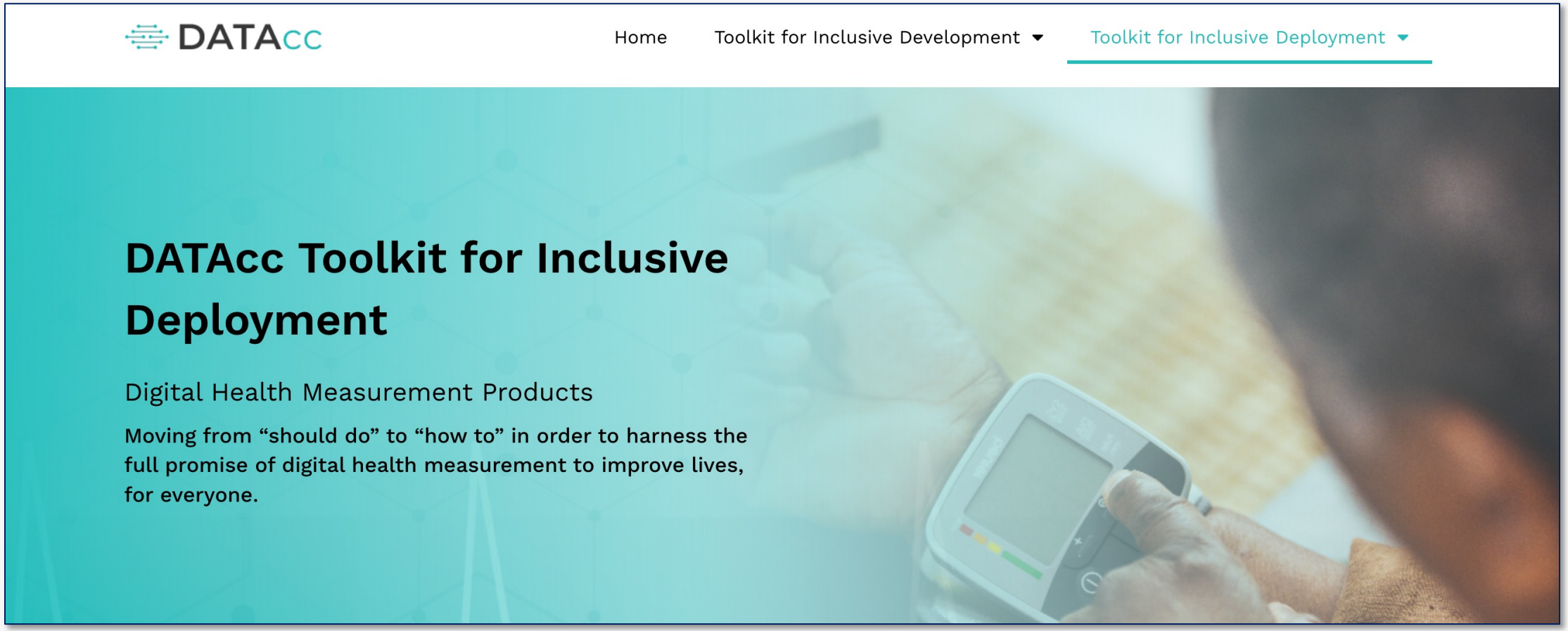


Figure 1 Overview of AI and ML Concepts

DATAcc Toolkit for Inclusive Deployment

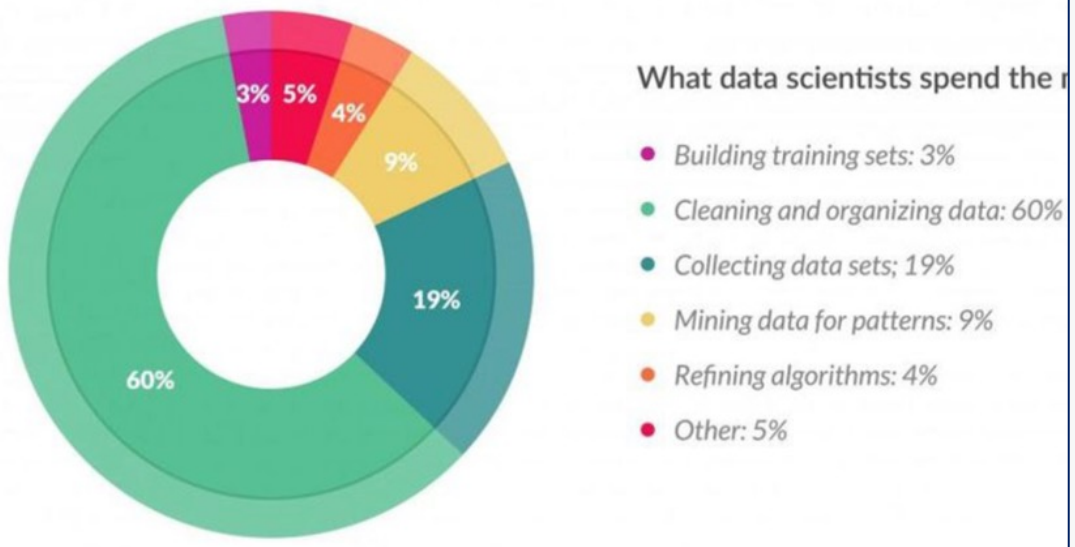
resources



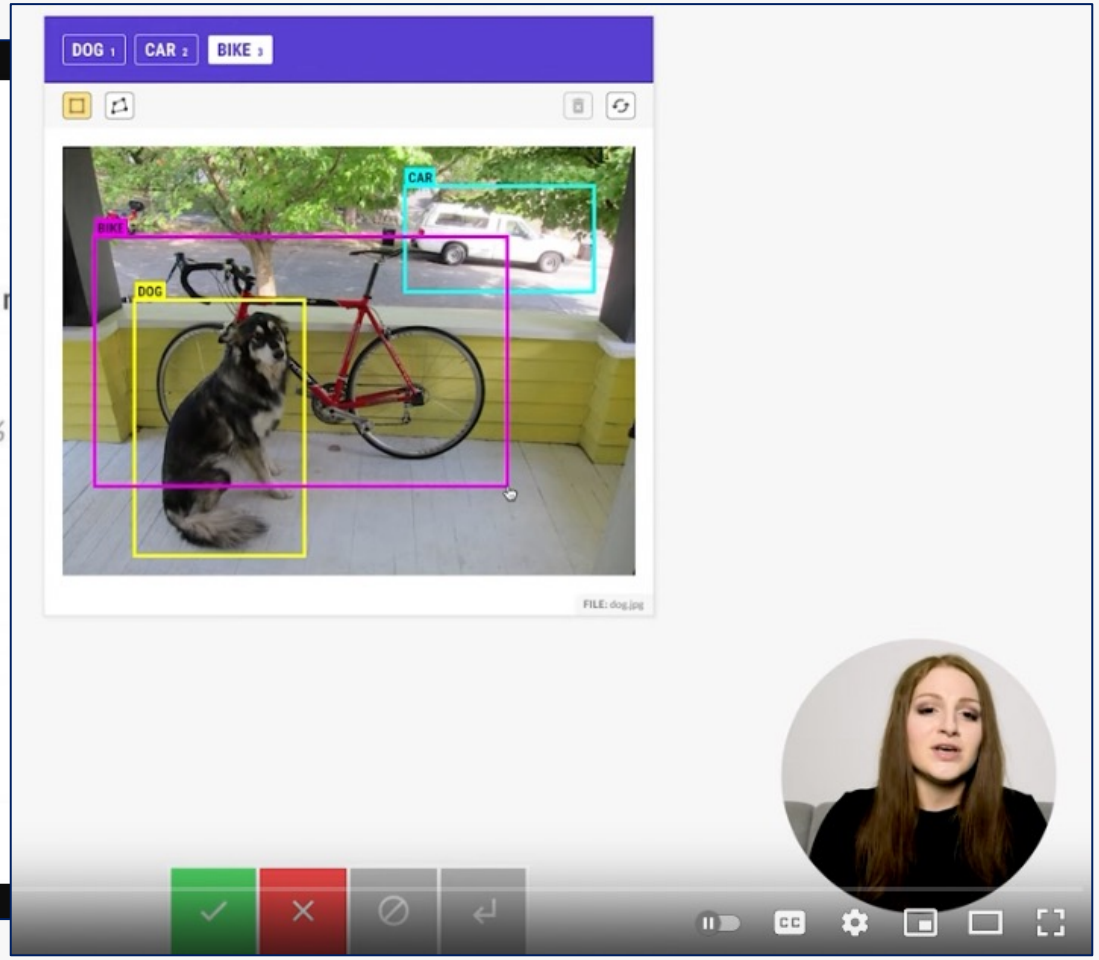
Prodigy: Radically efficient machine teaching. An annotation tool powered by active learning

resources

Data preparation accounts for about 80% of the work of data scientists



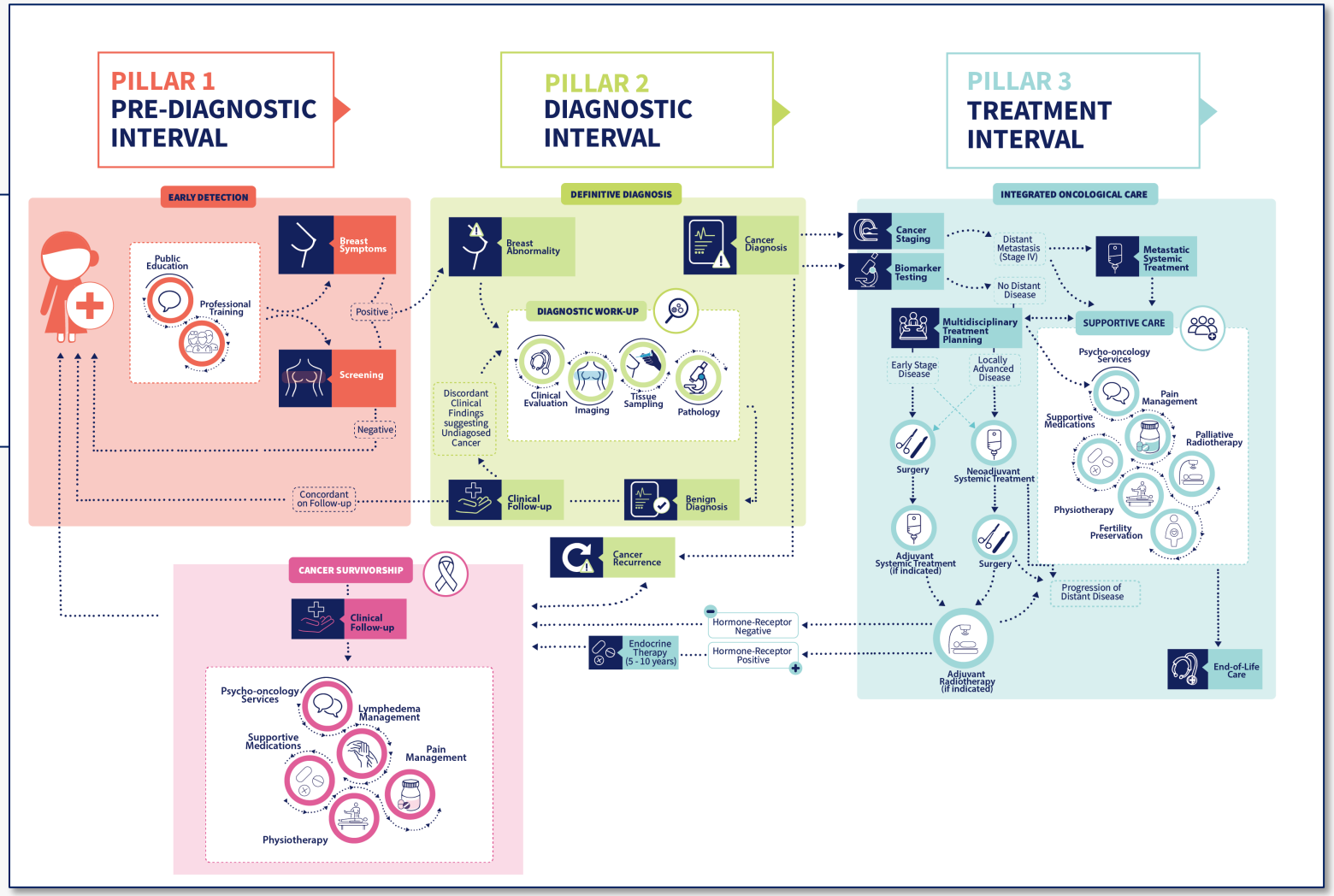
Forbes. Gil Press. Mar 23, 2016



WHO Breast Cancer Initiative

resources

World Health Organization



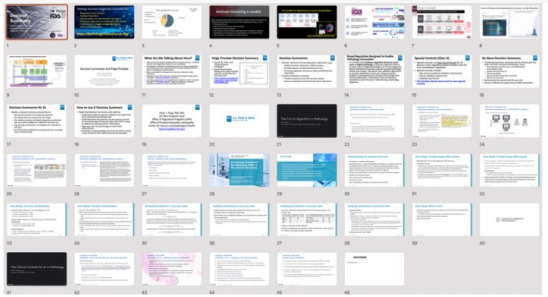
Project Updates

- FDA cleared comments from Decision Summary session (presentation June 2022 are available on website

Detailed discussion session:

- Q&A from presenters (download)

Download the entire presentation here



- DPA & PIcc intro slides (download)
- Dr. Peter Yang, FDA: Decision Summaries and Paige Prostate (download)
- Emre Gulturk, Paige: The First AI Algorithm in Pathology (download)
- Dr. Jansen Seheult, Mayo/CAP: A proposed framework for deploying AI/ML in the clinical laboratory (download)
- Dr. David Klimstra, Paige: The Clinical Outlook for AI in Pathology (download)

Questions & Answers

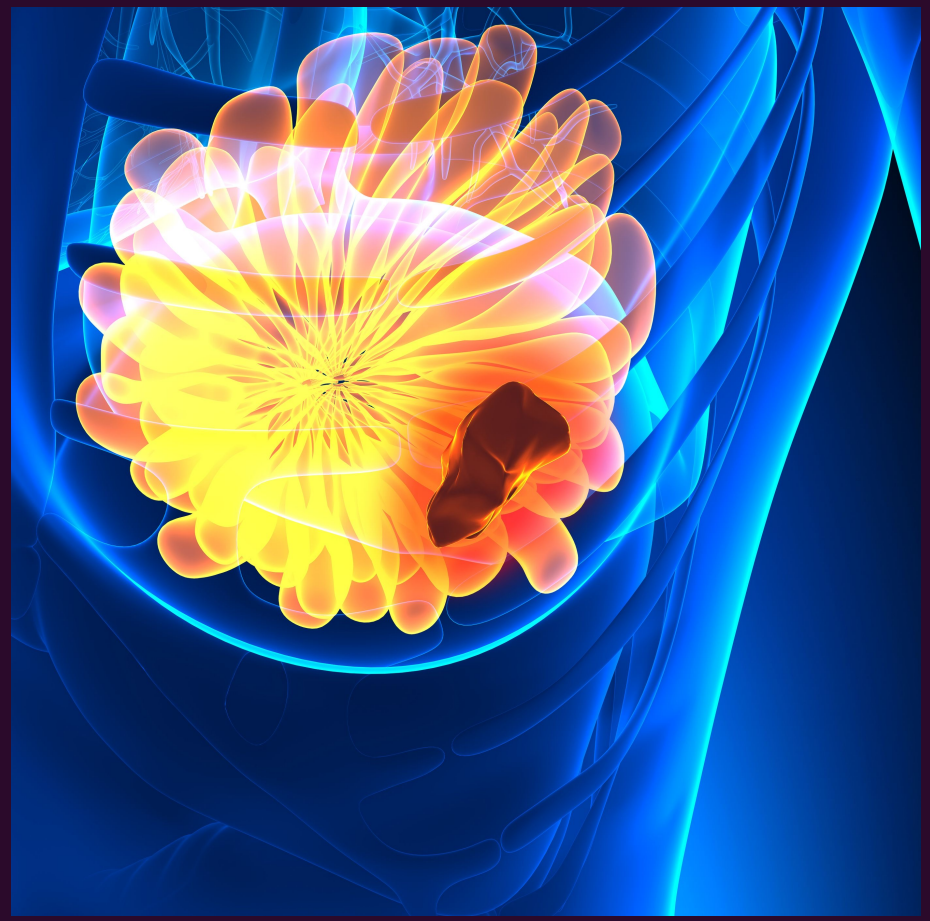
Question from Alice Geaney: Will the FDA be defining consensus standards for Paige Prostate device product code?

Answer from Peter Yang: A guidance document might be one way to provide such information. However, for the different kinds of applications there would be a lot of details needed. My thinking is less a general guidance, but rather taking the individual device function into account to assure that it is analytically and clinically valid for its purpose.

Question from Joy Kavanagh: Peter you very rightly recommend early engagement with FDA via pre-submission process, can you comment on current wait time for pre-subs, i.e. has this returned to normal

Project proposals:

- HER2-low (NEJM paper + ASCO, now change in paradigm of breast cancer testing)
- Abemaciclib/Ki-67 in breast cancer project



ctDNA Out of the Dark session

- Friends hosted two sessions on the topic
- review of draft guidance is up
- draft is being prepared and will be circulated for comments

Friends of Cancer Research Virtual Meeting

Expediting Drug Development: Use of ctDNA as an Early Endpoint

Wednesday, July 20, 2022

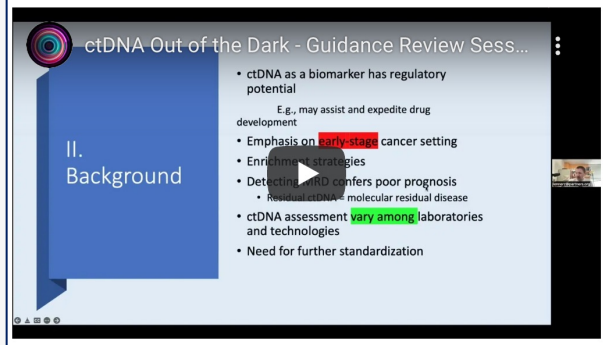
11:30AM EDT - 1:00PM EDT

Thank you to all that attended!

Click HERE to Watch the Full Meeting

Click HERE to access the Meeting Discussion Document.

July 21 Meeting



Meeting slides

Content:

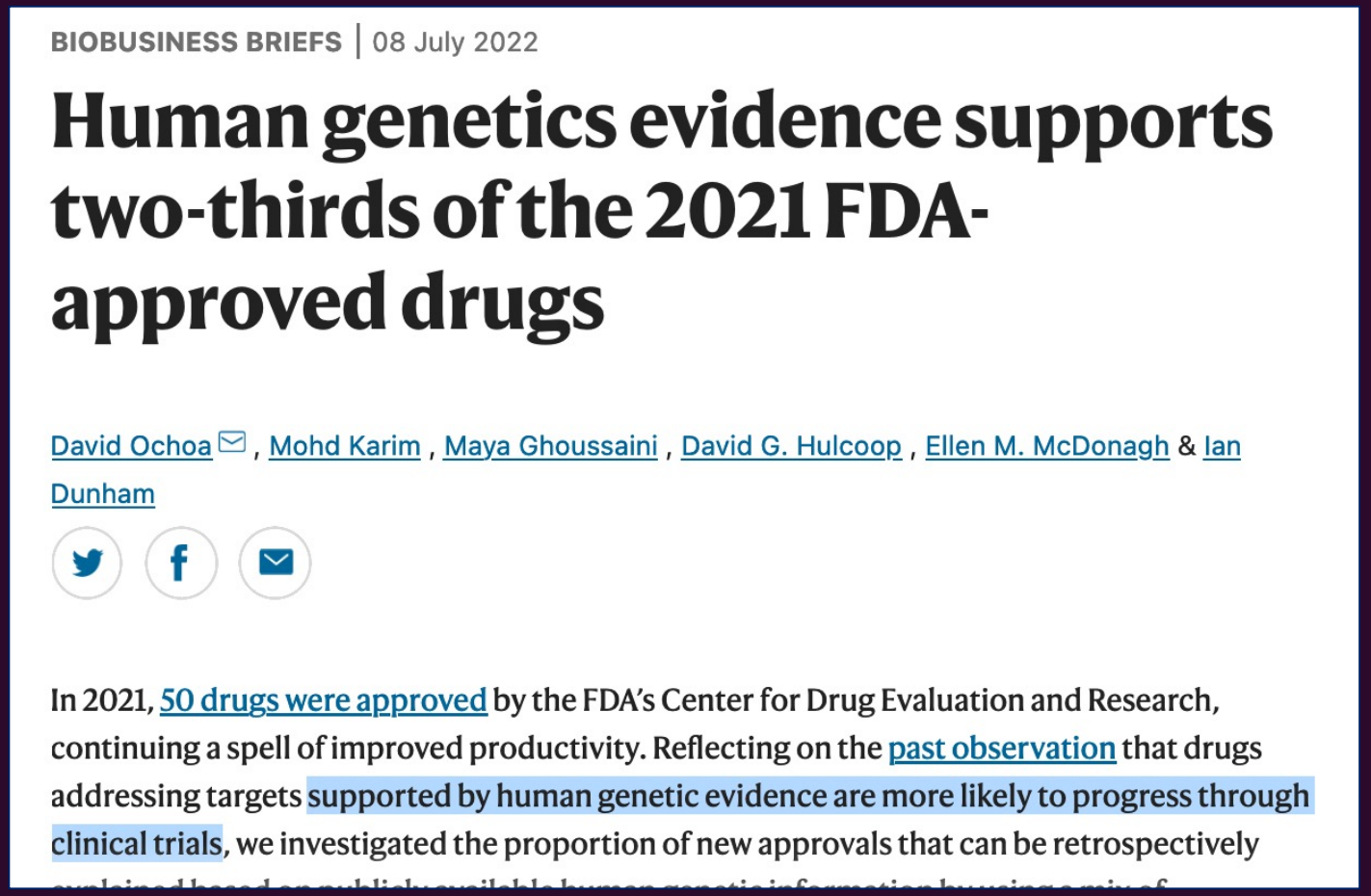
- Search for FDA Guidances (link)
- Hematologic Malignancies: Regulatory Considerations for Use of Minimal Residual Disease in Development of Drug and Biological Products for Treatment Guidance for Industry (link) (download)
- Multiple Endpoints in Clinical Trials (link) (download)

Featured Papers

Ochoa et al.

Establish human genetics evidence supports two-thirds of the 2021 FDA-approved drugs

featured papers



BIOBUSINESS BRIEFS | 08 July 2022

Human genetics evidence supports two-thirds of the 2021 FDA-approved drugs

David Ochoa , Mohd Karim , Maya Ghoussaini , David G. Hulcoop , Ellen M. McDonagh & Ian Dunham

In 2021, 50 drugs were approved by the FDA's Center for Drug Evaluation and Research, continuing a spell of improved productivity. Reflecting on the past observation that drugs addressing targets supported by human genetic evidence are more likely to progress through clinical trials, we investigated the proportion of new approvals that can be retrospectively

Mackey et al.

Establishing a blockchain-enable indigenous data sovereignty framework for genomic data

CellPress

Cell
Leading Edge

Commentary

Establishing a blockchain-enabled Indigenous data sovereignty framework for genomic data

Tim K. Mackey,[1,2,3,4] Alec J. Calac,[3,5,6] B S Chenna Keshava,[7] Joseph Yracheta,[8] Krystal S. Tsosie,[8] and Keolu Fox[1,8,9,*]
[1]Global Health Program, Department of Anthropology, University of California, San Diego, San Diego, CA, USA
[2]S-3 Research LLC, San Diego, CA, USA
[3]Global Health Policy and Data Institute, San Diego, CA, USA
[4]BlockLAB, San Diego Supercomputer Center, San Diego, CA, USA
[5]University of California, San Diego, School of Medicine, San Diego, CA, USA

both the representatives of different Indigenous groups, but also the Indigenous community members themselves, as well as limited participation of external non-Indigenous entities that seek to access data in the system for scientific purposes agreed upon by the community. In this context, we adopt a "consortium"-

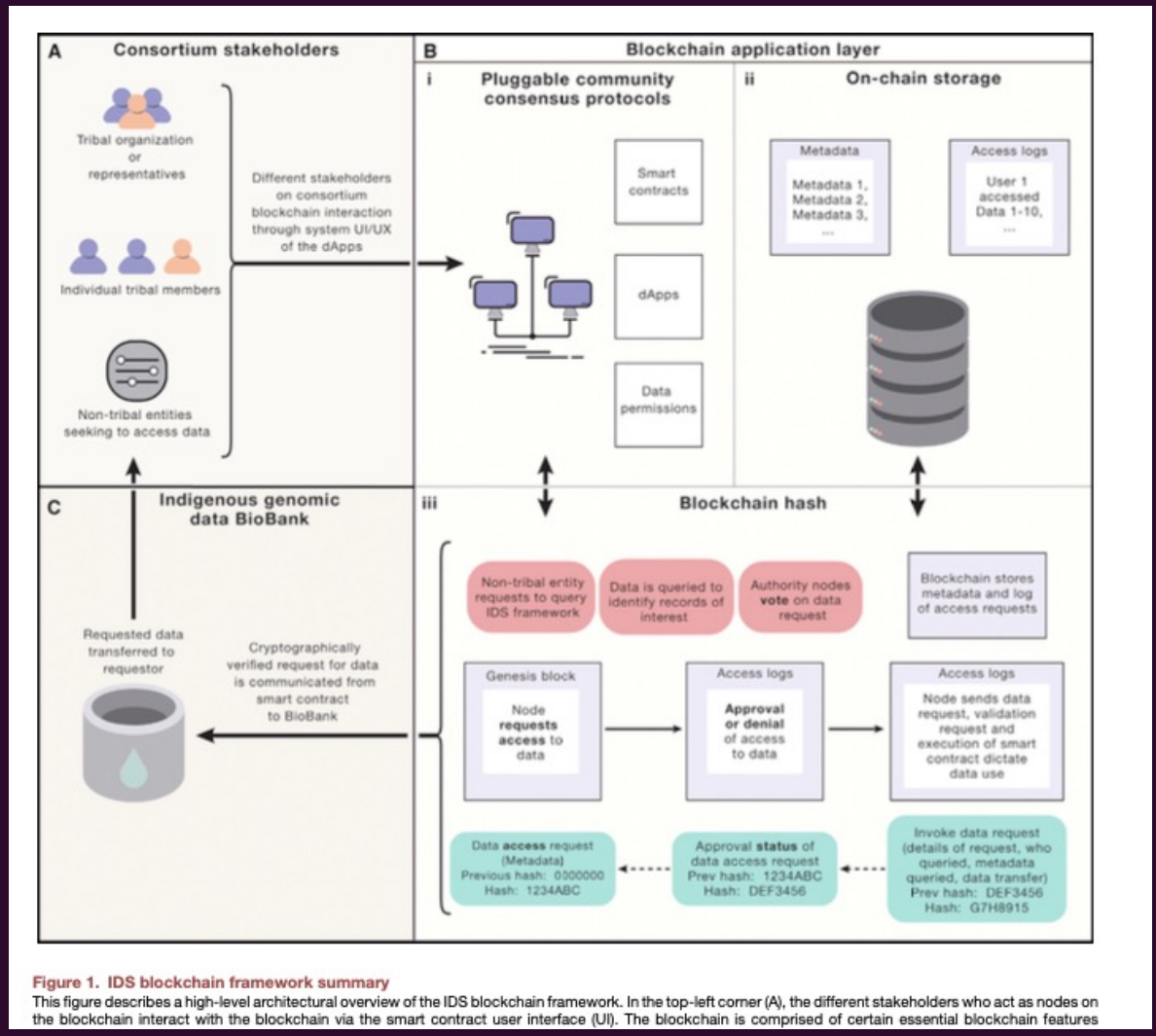


Figure 1. IDS blockchain framework summary
This figure describes a high-level architectural overview of the IDS blockchain framework. In the top-left corner (A), the different stakeholders who act as nodes on the blockchain interact with the blockchain via the smart contract user interface (UI). The blockchain is comprised of certain essential blockchain features

featured papers

Antonelli et al.
The Medical Segmentation Decathlon

ARTICLE

https://doi.org/10.1038/s41467-022-30695-9 OPEN

The Medical Segmentation Decathlon

Michela Antonelli[1,42✉], Annika Reinke[2,3,4,42], Spyridon Bakas[5,6,7], Keyvan Farahani[8], Annette Kopp-Schneider[9], Bennett A. Landman[10], Geert Litjens[11], Bjoern Menze[12], Olaf Ronneberger[13], Ronald M. Summers[14], Bram van Ginneken[11], Michel Bilello[5], Patrick Bilic[15], Patrick F. Christ[15], Richard K. G. Do[16], Marc J. Gollub[16], Stephan H. Heckers[17], Henkjan Huisman[11], William R. Jarnagin[18], Maureen K. McHugo[17], Sandy Napel[19], Jennifer S. Golia Pernicka[16], Kawal Rhode[1], Catalina Tobon-Gomez[1], Eugene Vorontsov[20], James A. Meakin[11], Sebastien Ourselin[1], Manuel Wiesenfarth[9], Pablo Arbeláez[21], Byeonguk Bae[22], Sihong Chen[23], Laura Daza[21], Jianjiang Feng[24], Baochun He[25], Fabian Isensee[26], Yuanfeng Ji[27], Fucang Jia[25], Ildoo Kim[28], Klaus Maier-Hein[29,30], Dorit Merhof[31,32], Akshay Pai[29,33], Beomhee Park[22], Mathias Perslev[33], Ramin Rezaiifar[34], Oliver Rippel[31], Ignacio Sarasua[35], Wei Shen[36], Jaemin Son[22], Christian Wachinger[35], Liansheng Wang[27], Yan Wang[37], Yingda Xia[38], Daguang Xu[39], Zhanwei Xu[24], Yefeng Zheng[23], Amber L. Simpson[40], Lena Maier-Hein[2,3,4,41,43] & M. Jorge Cardoso[1,43]

featured papers

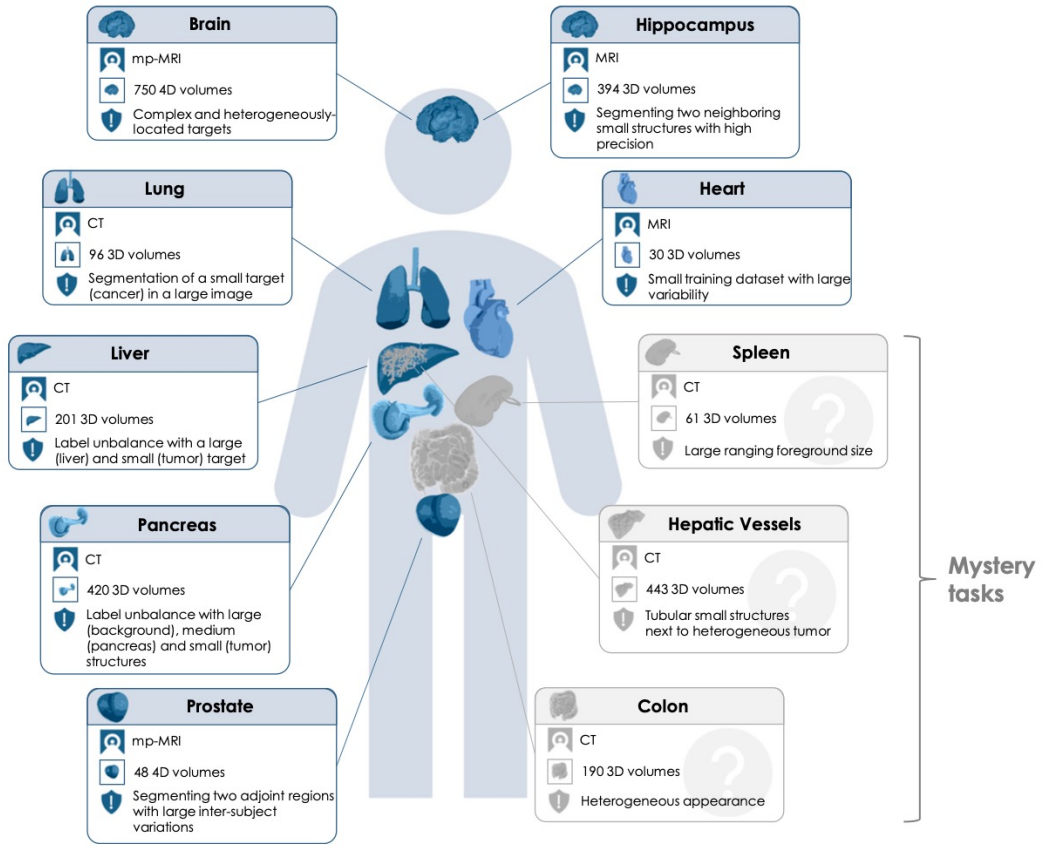


Fig. 1 Overview of the ten different tasks of the Medical Segmentation Decathlon (MSD). The challenge comprised different target regions, modalities and challenging characteristics and was separated into seven known tasks (blue; the development phase: brain, heart, hippocampus, liver, lung, pancreas, prostate) and three mystery tasks (gray; the mystery phase: colon, hepatic vessels, spleen). MRI magnetic resonance imaging, mp-MRI multiparametric-magnetic resonance imaging, CT computed tomography.

Rojansky et al.

Rapid deployment of whole slide imaging for primary diagnosis in surgical pathology at Stanford Medicine

Rapid Deployment of Whole Slide Imaging for Primary Diagnosis in Surgical Pathology at Stanford Medicine

Responding to Challenges of the COVID-19 Pandemic

Rebecca Rojansky, MD, PhD; Iny Jhun, MD, PhD; Alex M. Dussaq, MD, PhD; Steven M. Chirieleison, MD, PhD; Jeffrey J. Nirschl, MD, PhD; Don Born, MD, PhD; Jennifer Fralick, PMP; William Hetherington, BS; Alison M. Kerr, MS; Jonathan Lavezo, MD; Daniel B. Lawrence, BA; Seth Lummus, DO, MS; Ronald Macasaet, BA; Thomas J. Montine, MD, PhD; Emily Ryan, MD; Jeanne Shen, MD; Jonathan Shoemaker, BSIT; Brent Tan, MD, PhD; Hannes Vogel, MD; Puneet Singh Waraich; Eric Yang, MD, PhD; April Young, MS; Ann Folkins, MD

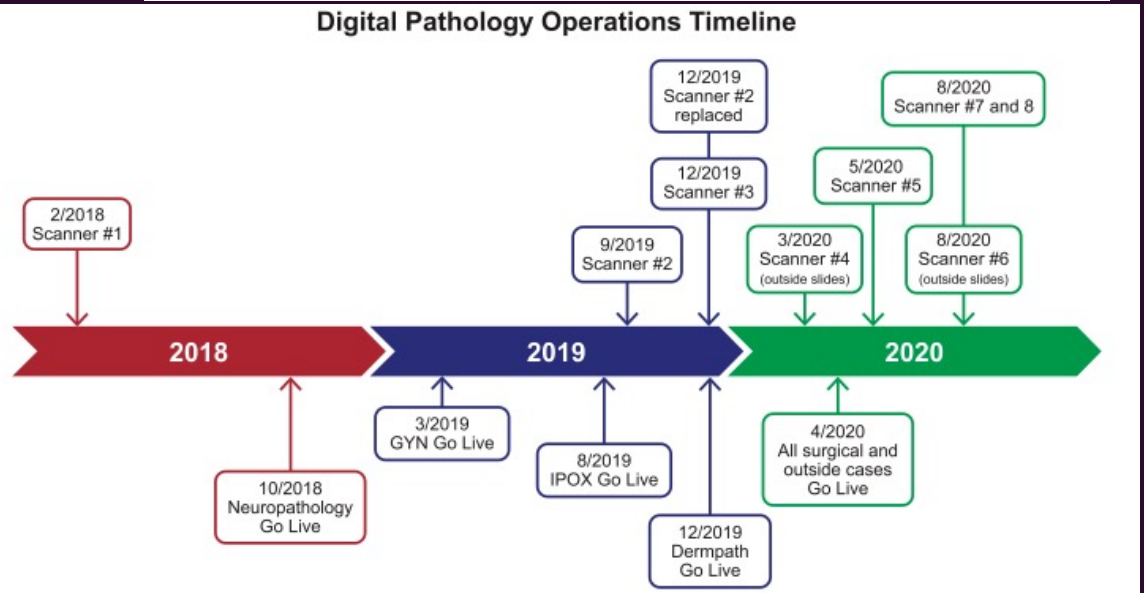


Figure 3. *Timeline of Stanford Pathology whole slide imaging (WSI) implementation beginning February 2018. Blue boxes show points at which scanners were added. Red boxes show the dates of the initial stepwise implementation of WSI for each of 4 subspecialty services followed by broad implementation across all surgical pathology and consult services in April 2020. Abbreviations: GYN, gynecologic pathology; IPOX, immunohistochemistry.*

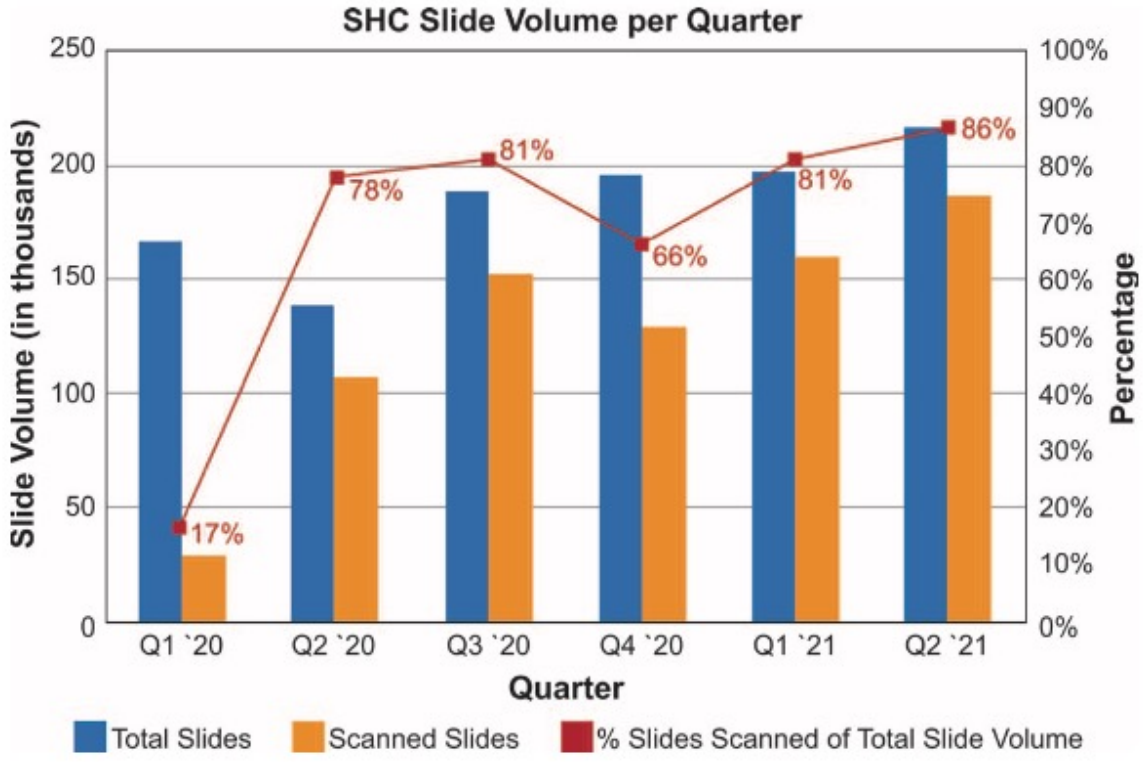


Figure 1. *Stanford Pathology scanning volume by quarter in 2020 and 2021. Total number of slides produced by Stanford Histology*

Kelly et al.

Job Stress, Burnout, Work-Life Balance, Well-Being, and Job Satisfaction Among Pathology Residents and Fellows

Job Stress, Burnout, Work-Life Balance, Well-Being, and Job Satisfaction Among Pathology Residents and Fellows

Melissa Kelly, PhD,[1] Ryan Soles, MS,[1] Edna Garcia, MPH,[2] and Iman Kundu, MPH[2]

From the [1]Evaluation, Measurement, and Assessment Department, Learning and Education Research Division, American Society for Clinical Pathology (ASCP), Chicago, IL; and [2]Institute for Science, Technology, and Public Policy, ASCP, Washington, DC.

Am J Clin Pathol April 2020;153:449-469

DOI: 10.1093/AJCP/AQAA013

Table 3

Frequency of Engaging in Hobbies, Recreational Activities, or Personal Interests Outside of Work by Work-Life Balance

	No. (%) With Poor or Fair Work-Life Balance		No. (%) With Good or Excellent Work-Life Balance	
Frequency of Engaging in Hobbies, Recreational Activities, and Personal Interests	Residents	Fellows	Residents	Fellows
Never	3 (5)	2 (13)	0 (0)	0 (0)
Up to once or twice a month	24 (41)	7 (44)	1 (3)	2 (22)
Up to three or four times a month	9 (16)	2 (13)	9 (26)	1 (11)
Up to once or twice a week	13 (22)	2 (13)	11 (31)	4 (44)
Up to three or four times a week	6 (10)	1 (6)	5 (14)	2 (22)
Almost every day	1 (2)	1 (6)	9 (26)	0 (0)
Other	2 (3)	1 (6)	0 (0)	0 (0)

featured papers

Ricciuti et al.

Association of high tumor mutation burden in non-small cell lung cancers with increased immune infiltration and improved clinical outcomes of PD-L1 blockade across PD-L1 expression levels

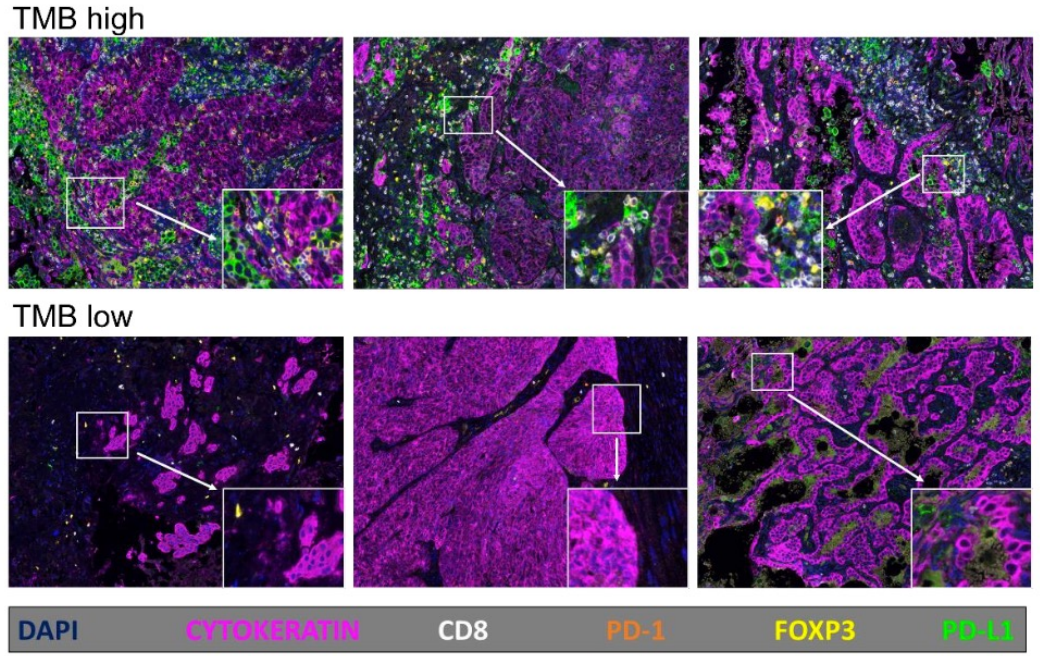
JAMA Oncology | Original Investigation

Association of High Tumor Mutation Burden in Non-Small Cell Lung Cancers With Increased Immune Infiltration and Improved Clinical Outcomes of PD-L1 Blockade Across PD-L1 Expression Levels

Biagio Ricciuti, MD; Xinan Wang, PhD; Joao V. Alessi, MD; Hira Rizvi, BA; Navin R. Mahadevan, MD; Yvonne Y. Li, PhD; Andrew Polio, MD; James Lindsay, MD; Renato Umeton, PhD; Rileen Sinha, PhD;

Table 2. Objective Response Rate, Progression-Free, and Overall Survival to PD-1/PD-L1 Blockade in High and Low TMB Non-Small Cell Lung Cancer According to PD-L1 Expression Subgroups

Outcome and PD-L1 tumor proportion score	Low TMB	High TMB	*P* value
Objective response rate, % (95% CI)			
<1%	8.7 (5.5-12.9)	46.7 (28.3-65.7)	<.001
1%-49%	18.7 (14.1-23.9)	50.0 (31.3-68.7)	<.001
≥50%	38.1 (33.3-43.0)	56.5 (41.1-71.1)	.02
Progression-free survival, median (95% CI), mo			
<1%	2.1 (2.0-2.4)	10.7 (8.2-24.4)	<.001
1%-49%	2.9 (2.5-3.6)	13.6 (8.6-NR)	<.001
≥50%	5.2 (4.6-6.2)	18.1 (8.6-NR)	<.001
Overall survival, median (95% CI), mo			
<1%	10.4 (7.9-13.6)	23.9 (16.7-NR)	.07
1%-49%	11.3 (9.6-14.7)	NR (21.2-NR)	<.001
≥50%	21.4 (17.5-25.9)	47.7 (35.4-NR)	.02



eFigure 21. Multiplexed Immunofluorescence for CD8, PD-1, Foxp3, PD-L1, in Three Index Cases With High TMB (**A**) and Three Index Cases With Low TMB (**B**).

Hutchinson & Grimm

Integrating digital pathology and mathematical modelling to predict spatial biomarker dynamics in cancer immunotherapy

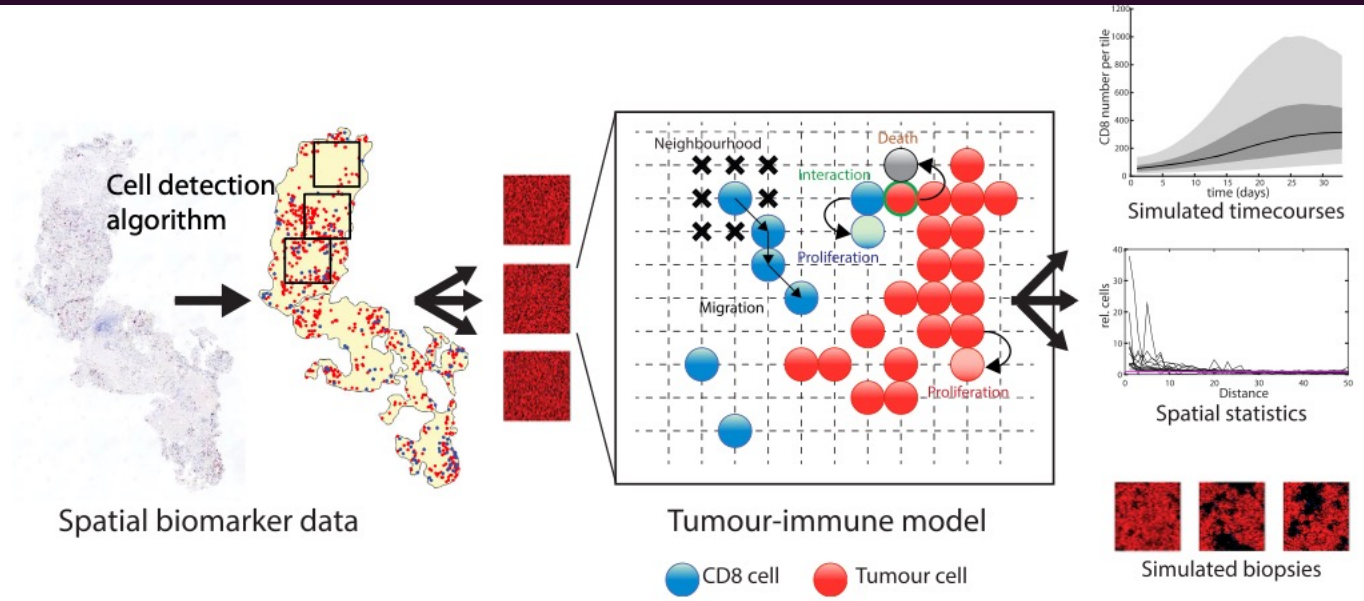


Fig. 1 Integrating digital pathology and mathematical modelling. For each patient sample, tissue sections of pre- and on-treatment biopsies were stained against CD8 and Ki67 and digitally analysed to extract the positions of CD8 cells and tumour cells. The image is subdivided into tiles which are used as an input to the model. In the agent-based model, cells at each grid site follow rules regarding their behaviours and interactions. The state of the model is recorded at each time step and the results can be visualised as timecourses and spatial summary statistics and simulated biopsy images.

npj Digital Medicine (2022) 92

Published in partnership with Seoul National University Bundang Hospital

featured papers

Shinohara et al.

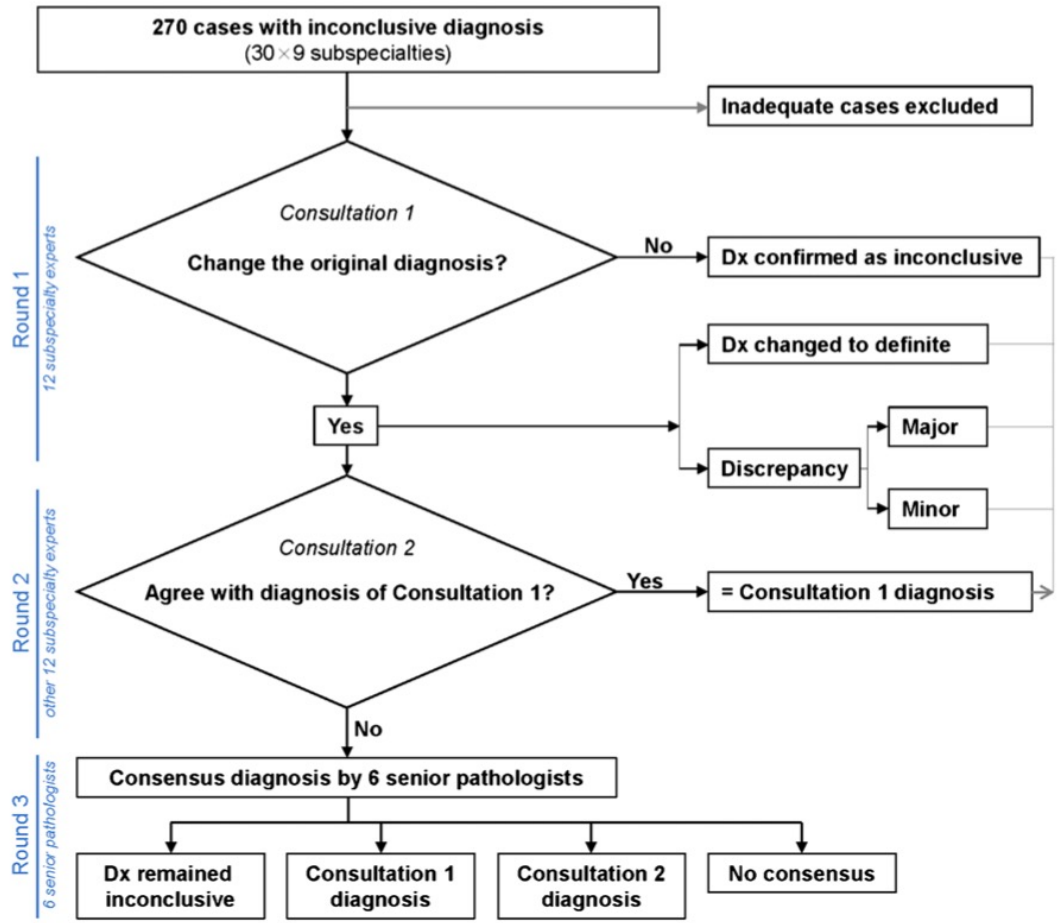
Substantial improvement of histopathological diagnosis by whole-slide image-based remote consultation

Substantial improvement of histopathological diagnosis by whole-slide image-based remote consultation

Shizu Shinohara[1] · Andrey Bychkov[2] · Jijgee Munkhdelger[2] · Kishio Kuroda[1] · Han-Seung Yoon[1] · Shota Fujimura[1] · Kazuhiro Tabata[1] · Bungo Furusato[1] · Daisuke Niino[1] · Shinpei Morimoto[1] · Takashi Yao[3] · Tomoo Itoh[4] · Hajime Aoyama[5] · Naoko Tsuyama[6] · Yoshiki Mikami[7] · Toshitaka Nagao[8] · Tohru Ikeda[9] · Noriyoshi Fukushima[10] · Oi Harada[2] · Takako Kiyokawa[11] · Naoki Yoshimi[5] · Shinichi Aishima[12] · Ichiro Maeda[13] · Ichiro Mori[14] · Koji Yamanegi[15] · Koichi Tsuneyama[16] · Ryohei Katoh[17] · Miki Izumi[18] · Yoshinao Oda[19] · Junya Fukuoka[1]

featured papers

Fig. 1 Flowchart of the study



Hassell et al. Pathology education powered by virtual and digital transformation

Pathology Education Powered by Virtual and Digital Transformation

Now and the Future

Lewis A. Hassell, MD; Syeda Fatima Absar, MD, MPH; Chhavi Chauhan, PhD; Suzanne Dintzis, MD, PhD; Carol F. Farver, MD; Samreen Fathima, MD; Eric F. Glassy, MD; Jeffery A. Goldstein, MD, PhD; Rama Gullapalli, MD, PhD; Jonhan Ho, MD, PhD; Lisa K. Koch, MD, PhD; James E. Madory, DO; Kamran M. Mirza, MD, PhD; Phuong Nhat Nguyen, MD, MS; Liron Pantanowitz, MD, MHA; Anil Parwani, MD, PhD, MBA; Rebecca Rojansky, MD, PhD; Robert P. Seifert, MD; Rajendra Singh, MD; Ehab A. ElGabry, MD; Marilyn Bui, MD

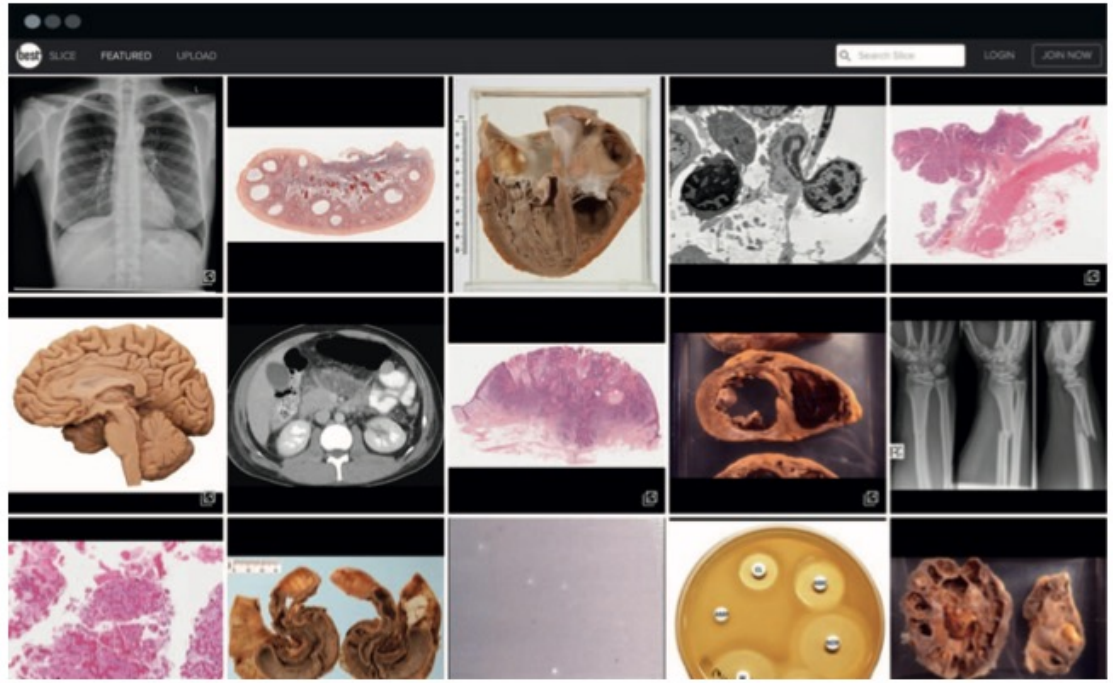


Table 1. Digital Pathology and Other Online Resources for Learning Surgical Pathology

Resource	Description	URL[a]
Cases		
American Society of Dermatopathology	Case of the month	https://www.asdp.org/education/case-study-of-the-month/
California Tumor Registry	Case of the month—static images and extensive discussion	http://www.cttr.org/
College of American Pathologists	Case of the month—general pathology, WSI	https://www.cap.org/member-resources/case-of-the-month
Genitourinary Pathology Society	GU pathology, case of the week, static images	https://www.gupathsociety.org/COW-2021-13
International Society of Urologic Pathology	Case of the month—GU pathology, WSI, need ISUP membership	https://isupweb.org/isup/
OSU	Case of the week	https://pathology.osu.edu/COTW/default.aspx
Pulmonary Pathology Society	Pulmonary pathology, static images, case of the month	https://www.pulmonarypath.org/cotm/cotm_current.html
UPMC	Case of the month, static images	https://path.upmc.edu/casemonth/ap-casemonth.html
Atlases		
Leeds	General WSI	https://www.virtualpathology.leeds.ac.uk/
MGH pathology	General pathology, frozen sections WSI	https://learn.mghpathology.org/index.php/WSI:study
Pathpresenter	Platform for sharing slides or images	https://pathpresenter.net/
Rosai Collection	General pathology, Imagescope	https://www.rosaicollection.org/
University of Michigan	General pathology, WSI	https://www.pathology.med.umich.edu/apps/slides/
University of Oklahoma	WSI, quizzes, atlas	https://www.ouhsc.edu/pathologyJTY/OUMC/Default.htm
University of Utah Webpath	Static images covering many areas	https://webpath.med.utah.edu/
Didactic		
Webpathology	Static images	https://www.webpathology.com/
Johns Hopkins Unknowns	Quiz format, static images (email address is requested to access)	http://apps.pathology.jhu.edu/sp/
PathCast	Video didactic lecture series, ongoing, dating to 2016	https://pathologycast.com/index.php?title=pathCast
PathologyOutlines	Opensource textbook with digital slides and video links on many topics	https://www.pathologyoutlines.com/
Other		
DAPA	Requires DPA membership (free to trainees)	https://digitalpathologyassociation.org/digital-anatomic-pathology-academy
Kiko	Platform to share medical data in many formats (requires account; free to obtain)	https://kikoxp.com

Abbreviations: DAPA, Digital Anatomic Pathology Academy; DPA, Digital Pathology Association; GU, genitourinary; ISUP, International Society of Urological Pathology; KiKo, Knowledge in, Knowledge out; MGH, Massachusetts General Hospital; OSU, The Ohio State University; UPMC, University of Pittsburgh Medical Center; WSI, whole slide images.

[a] All URLs accessed December 21, 2021.

Hongkui Zeng

What is a cell type and how to define it?

Cell
Leading Edge

Review

What is a cell type and how to define it?

Hongkui Zeng[1,*]
[1]Allen Institute for Brain Science, Seattle, WA 98109, USA
*Correspondence: hongkuiz@alleninstitute.org
https://doi.org/10.1016/j.cell.2022.06.031

SUMMARY

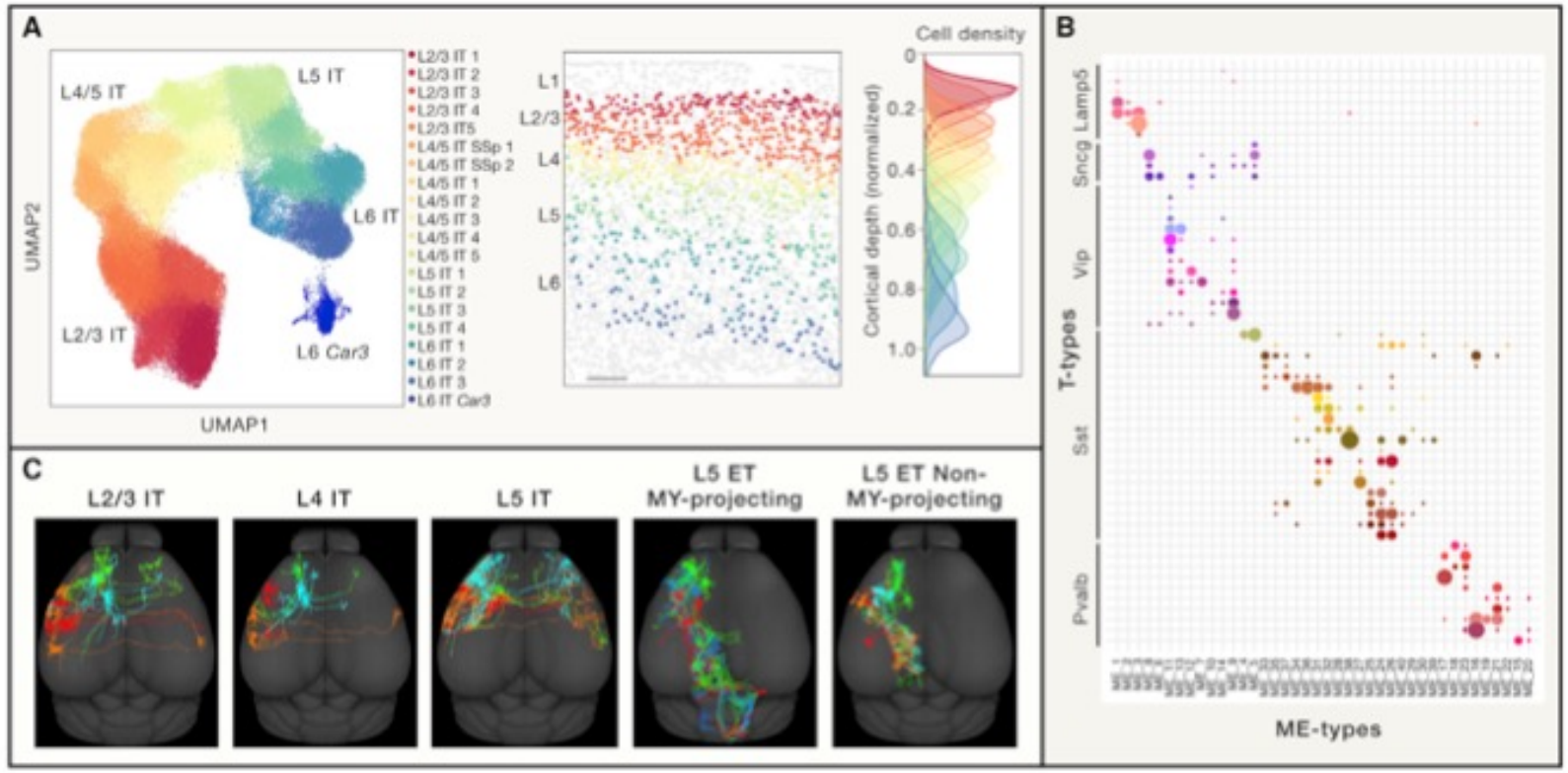


Figure 3. Multimodal correspondence of cell type phenotypic properties

(A) MERFISH data from mouse motor cortex shows that continuous variation of glutamatergic IT transcriptomic types is correlated with their continuous spatial

featured papers

Neumann et al.

Genomic architecture of FGFR2 fusions in cholangiocarcinoma and its implication for molecular testing

British Journal of Cancer

www.nature.com/bjc

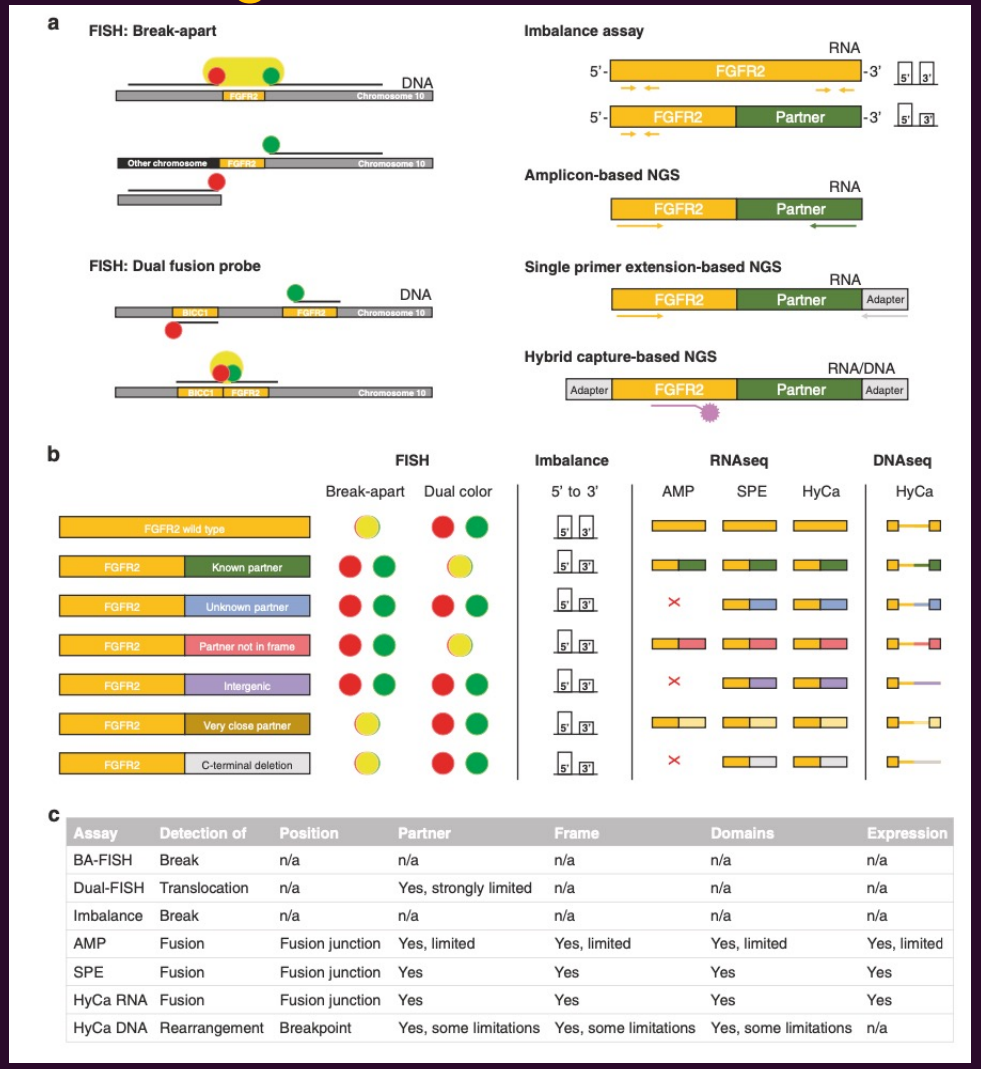
ARTICLE OPEN

Check for updates

Molecular Diagnostics

Genomic architecture of FGFR2 fusions in cholangiocarcinoma and its implication for molecular testing

Olaf Neumann[1,2,3], Timothy C. Burn[4,14], Michael Allgäuer[1], Markus Ball[1,5], Martina Kirchner[1], Thomas Albrecht[1], Anna-Lena Volckmar[1], Susanne Beck[1], Volker Endris[1], Hannah Goldschmid[1], Ulrich Lehmann[6], Huriye Seker-Cin[1], Sebastian Uhrig[7,8], Stephanie Roessler[1], Jan Budczies[1,2], Stefan Fröhling[2,3,8,9], Thomas Longerich[1,10], Alex H. Wagner[11,12], Arndt Vogel[13], Peter Schirmacher[1,2,3,10], Albrecht Stenzinger[1,2,3,5]✉ and Daniel Kazdal[1,2,3,5]✉



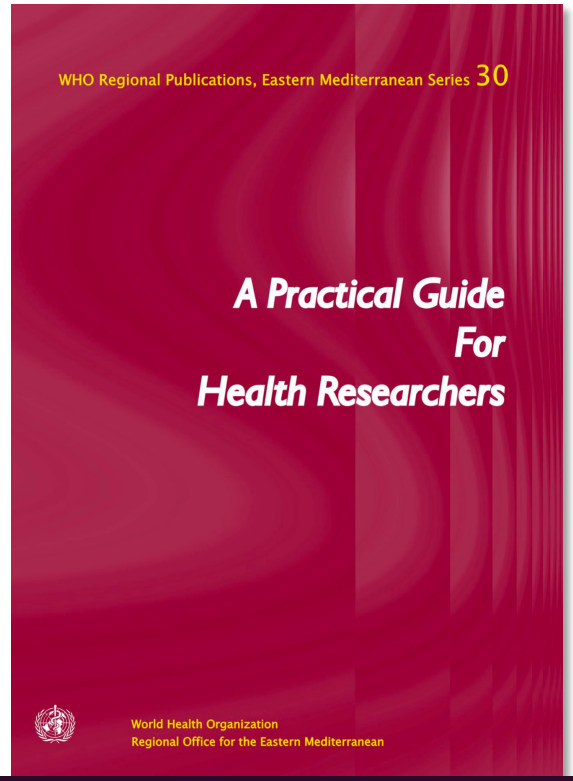
c

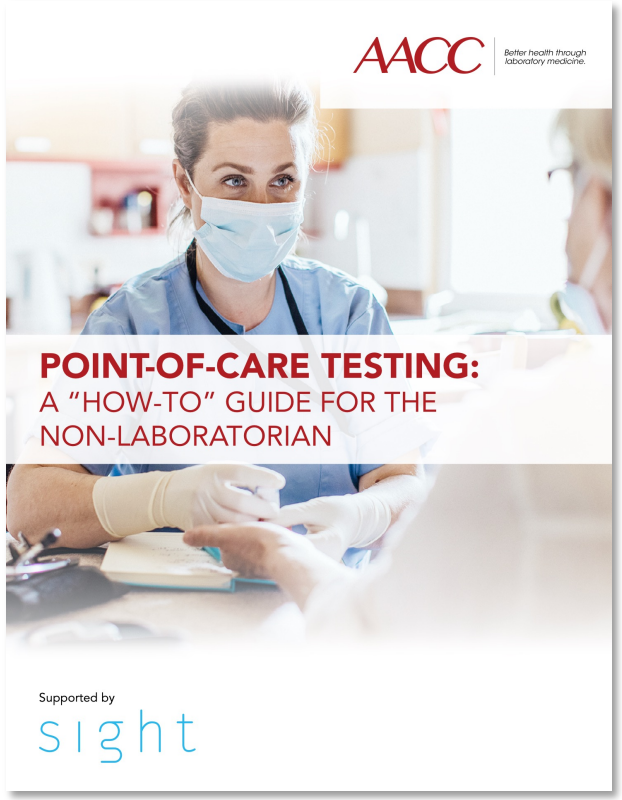
Assay	Detection of	Position	Partner	Frame	Domains	Expression
BA-FISH	Break	n/a	n/a	n/a	n/a	n/a
Dual-FISH	Translocation	n/a	Yes, strongly limited	n/a	n/a	n/a
Imbalance	Break	n/a	n/a	n/a	n/a	n/a
AMP	Fusion	Fusion junction	Yes, limited	Yes, limited	Yes, limited	Yes, limited
SPE	Fusion	Fusion junction	Yes	Yes	Yes	Yes
HyCa RNA	Fusion	Fusion junction	Yes	Yes	Yes	Yes
HyCa DNA	Rearrangement	Breakpoint	Yes, some limitations	Yes, some limitations	Yes, some limitations	n/a

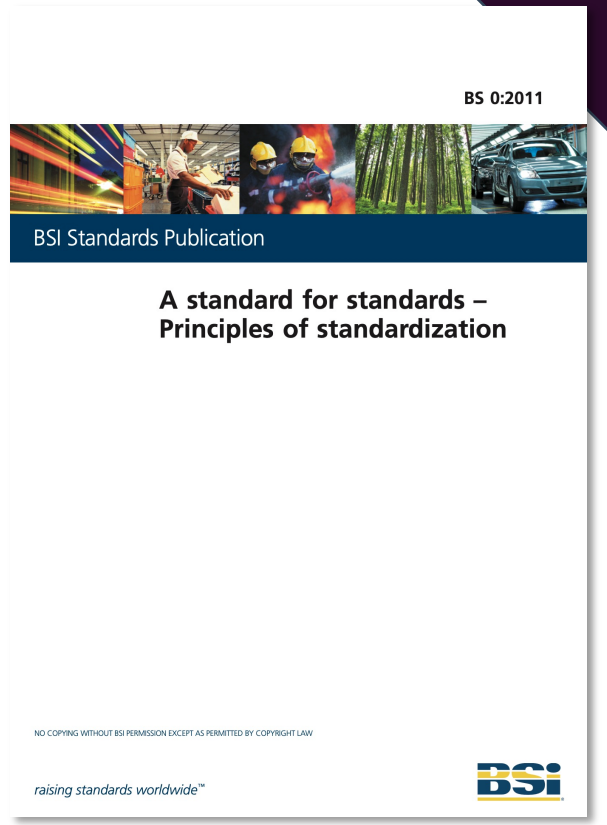
featured papers

Other resources

resources







Thank you

Next month's **steering committee** on

August 31, 2022 at 3:00-4:00 PM Eastern Time

Next event on

August 5, 2022 at 12:00-1:00 PM Eastern Time

Evaluating Medical Imaging Devices and Image-Based Algorithms with the Clinician in the Loop

Brandon Gallas, PhD

FDA/CDFH/OSEL/DIDSR