Plcc Alliance

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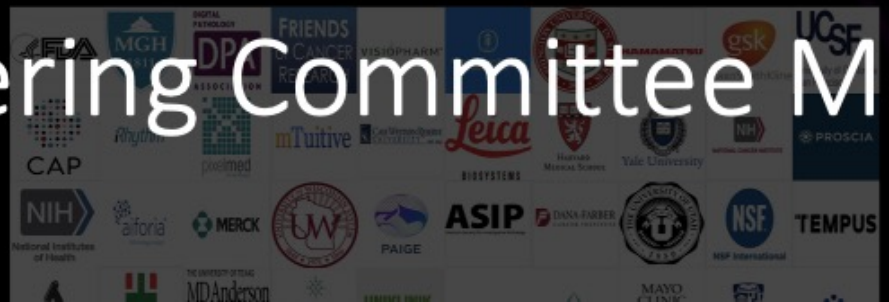
Pathology Innovation Collaborative Community

Plcc

The Alliance for Digital Pathology

A collaborative community with FDA participation



Steering Committee Meeting

April 2023

FDA

Contains Nonbinding Recommendations

Draft – Not for Implementation

Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

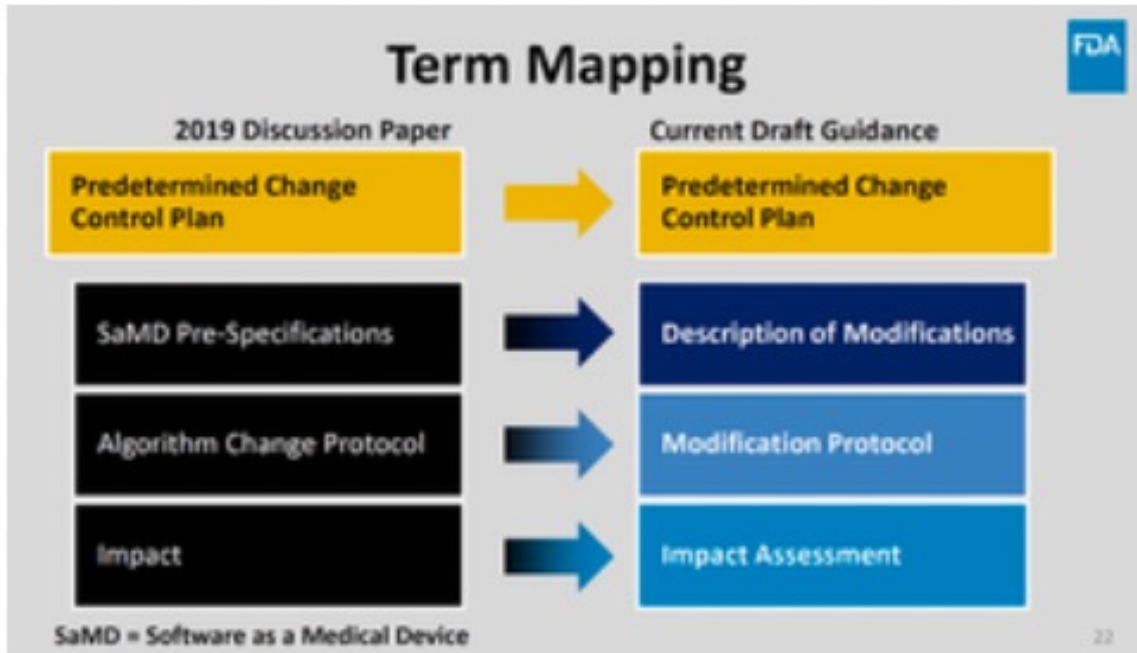
Document issued on April 3, 2023.

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

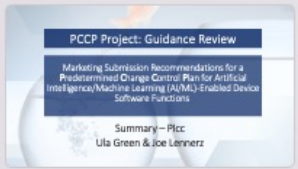
For questions about this document regarding CDRH-regulated devices, contact digitalhealth@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact ocod@fda.hhs.gov. For questions about this document regarding CDER-regulated products, contact druginfo@fda.hhs.gov. For questions about this document regarding combination products, contact the Office of Combination Products at combination@fda.gov.

FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research
Center for Drug Evaluation and Research
Office of Combination Products in the Office of the Commissioner



Download the slides from the webinar.



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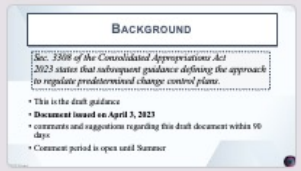

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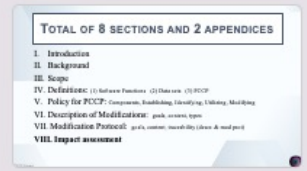

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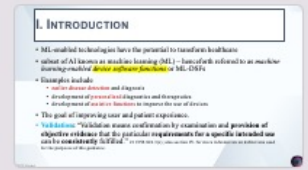

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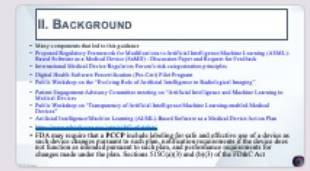

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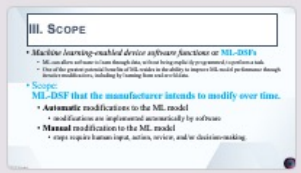

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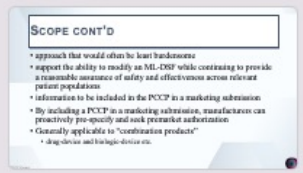

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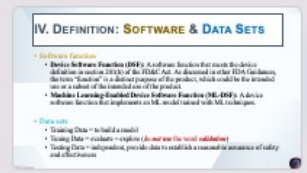

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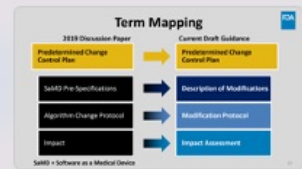

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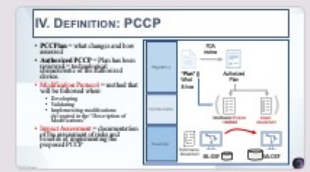

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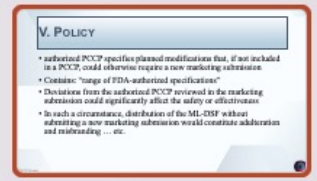

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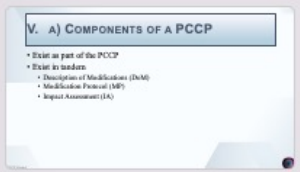

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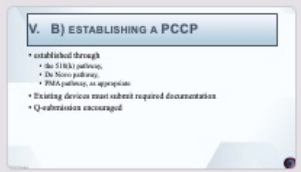

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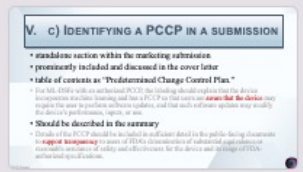

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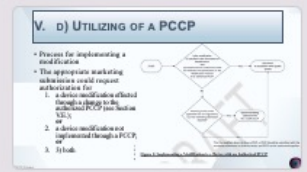

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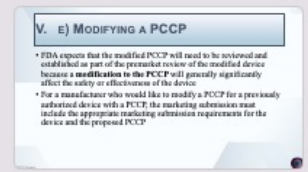

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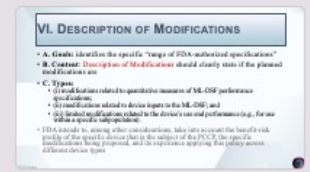

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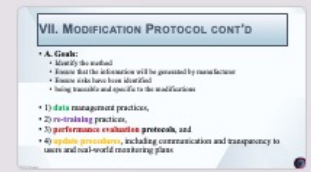

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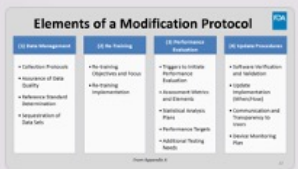

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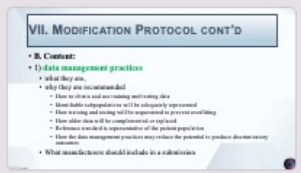

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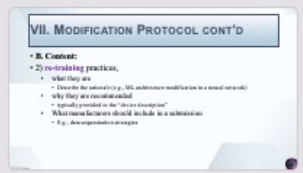

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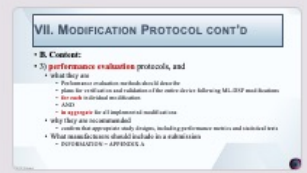

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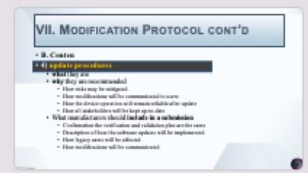

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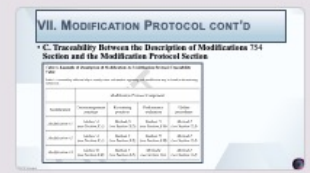

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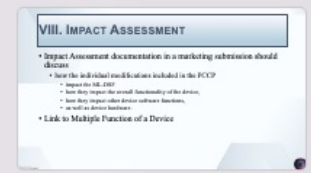

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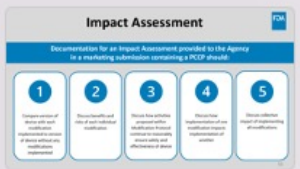

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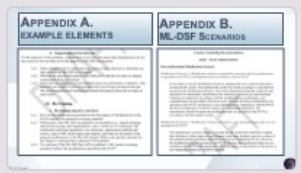

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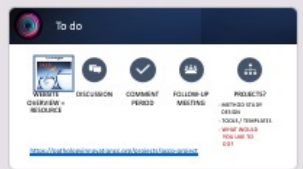

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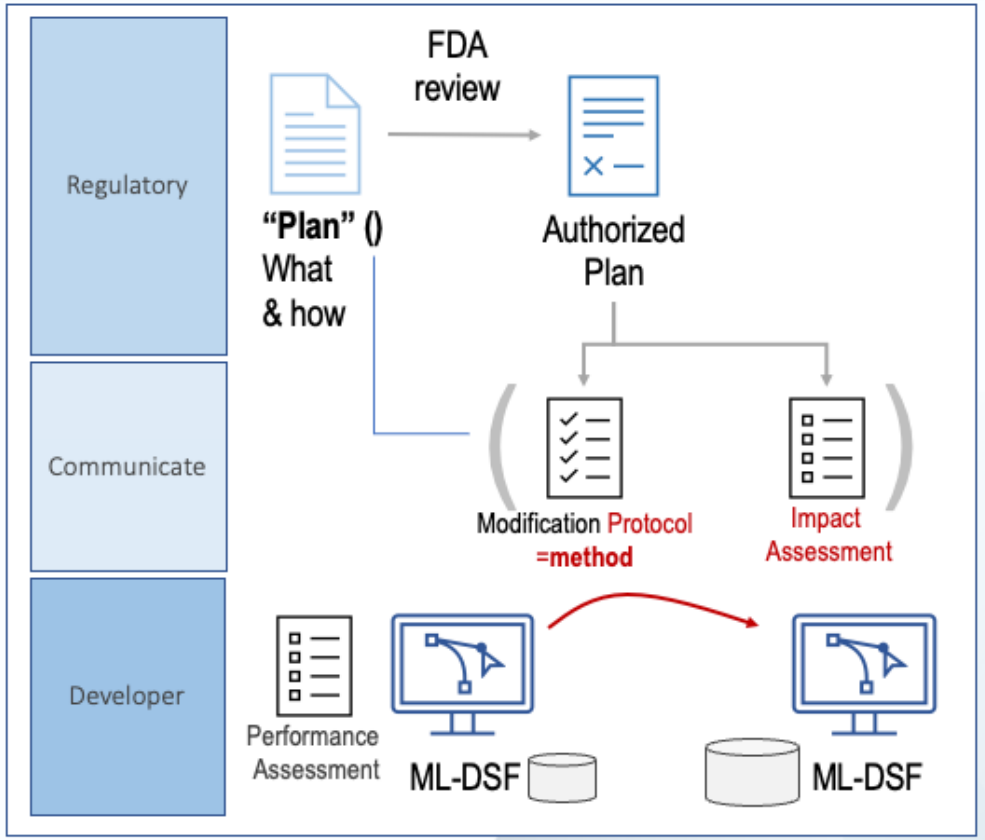
IV. Definition: PCCP

- **PCCPlan** = what changes and how assessed
- **Authorized PCCP** = Plan has been reviewed = technological characteristic of the authorized device.
- Modification Protocol = method that will be followed when:
  - Developing
  - Validating
  - Implementing modifications delineated in the "Description of Modifications"
- Impact Assessment = documentation of the assessment of risks and benefits of implementing the proposed PCCP



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TYPE Review
PUBLISHED 19 January 2023
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SPECIALTY SECTION
This article was submitted to Regulatory Science, a section of the journal Frontiers in Medicine

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ACCEPTED 13 December 2022
PUBLISHED 19 January 2023

New science, drug regulation, and emergent public health issues: The work of FDA's division of applied regulatory science

Kimberly Chiu[1†], Rebecca Racz[1†], Keith Burkhart[1], Jeffry Florian[1], Kevin Ford[1], M. Iveth Garcia[1], Robert M. Geiger[1], Kristina E. Howard[1], Paula L. Hyland[1], Omnia A. Ismaiel[1], Naomi L. Kruhlak[1], Zhihua Li[1], Murali K. Matta[1], Kristin W. Prentice[1,2], Aanchal Shah[1,2], Lidiya Stavitskaya[1], Donna A. Volpe[1], James L. Weaver[1], Wendy W. Wu[1], Rodney Rouse[1‡] and David G. Strauss[1*‡]

[1]Division of Applied Regulatory Science, Office of Clinical Pharmacology, Office of Translational Science, Center for Drug Evaluation and Research, United States Food and Drug Administration, Silver Spring, MD, United States, [2]Booz Allen Hamilton, McLean, VA, United States

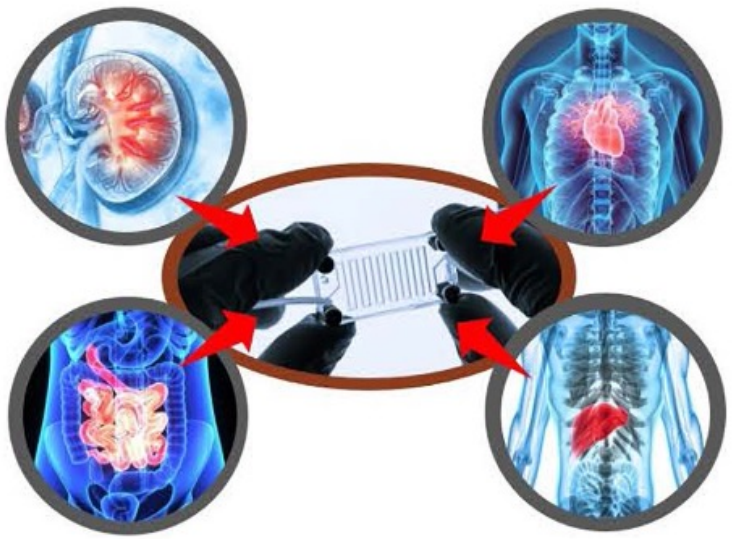

FIGURE 10
Division of applied regulatory science (DARS) is studying the utility of complex *in vitro* models, including with induced pluripotent stem cells (iPSCs) and microphysiological systems to reduce and replace animal testing.

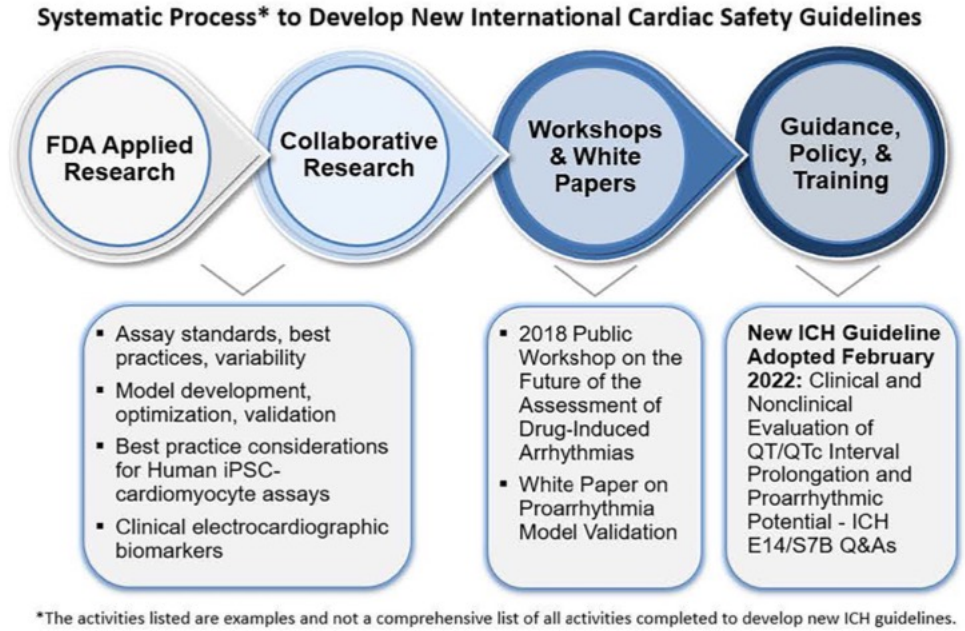

FIGURE 11
Under the comprehensive *in vitro* proarrhythmia assay (CiPA) initiative, division of applied regulatory science (DARS) (along with colleagues from CDER's office of new drugs) developed a non-clinical model (94) to evaluate the risk of drugs causing abnormal heart rhythms with a high level of predictivity. DARS also leads research in collaboration with external consortia to overhaul the approach to assessing the risk of abnormal heart rhythms for all new drugs and update regulatory guidelines.

LEGISLATIVE UPDATES

VALID
ACT
2023

.....

(Original Signature of Member)

118TH CONGRESS
1ST SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act with respect to in vitro clinical tests, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. BUCSHON introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to in vitro clinical tests, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

(a) SHORT TITLE.—This Act may be cited as the ''Verifying Accurate Leading-edge IVCT Development Act of 2023'' or the ''VALID Act of 2023''.

SEC. 2. DEFINITIONS.

(a) IN GENERAL.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended—

Diversity & Inclusion

Why Diverse Clinical Trial Participation Matters

Aaron L. Schwartz, M.D., Ph.D., Marcella Alsan, M.D., Ph.D., Alanna A. Morris, M.D., and Scott D. Halpern, M.D., Ph.D.

Marginalized racial and ethnic groups, women, and other historically disenfranchised

PERSPECTIVE

WHY DIVERSE CLINICAL TRIAL PARTICIPATION MATTERS

restrictions on equitable access to clinical services that continue to the present day. Among many

perceptions that a study and its findings are legitimate. Indeed, the benefits of inclusiveness might extend beyond the particular clinical scenario being studied to include reducing medical mistrust among marginalized communities more broadly. It will be

Goals of Increasing Diversity in Clinical Trials.

Goal	Key Challenges	Implications
Building trust in medical research and institutions	Distrust of medical and scientific professions can be an important obstacle to receiving effective medical care.	The effect on public trust of the design and conduct of clinical trials can be as important to public health as trials' results. Investments should be made in elucidating how clinical trial practices affect public trust.
Promoting fairness for potential participants and their communities	Opportunities to participate in trials are limited. Preferences, resources, and trust all affect willingness to participate in trials. Health systems' capacities to conduct trials vary among communities.	Overcoming unjust barriers to participation for disenfranchised groups will require affirmative outreach and recruitment actions. Grading trials on inclusive outreach and recruitment practices, rather than solely enrollment demographics, may better reflect recruitment equity. Investing in trial capacity in marginalized communities may benefit such communities broadly by improving adoption of innovations.
Generating biomedical knowledge	Sample sizes are often too small to permit assessment of treatment efficacy within particular subgroups. Clinically significant differences in treatment efficacy between groups that are underrepresented and those that are overrepresented in trials may not be common. Efforts to diversify trials address only some of the barriers to efficient patient recruitment.	Investigators should acknowledge that more inclusive trials may not show whether a treatment is effective for certain patient subgroups or meaningfully shift estimates of the treatment's efficacy. Shifting the focus of trials to diseases that disproportionately affect marginalized groups may more effectively generate knowledge benefiting these groups. Future meta-research could clarify the importance and detectability of heterogeneous treatment effects.

We believe the central goals of reforming the research process should be building trust among underserved communities and treating potential participants fairly.

Resources

nature communications

Article

https://doi.org/10.1038/s41467-023-37438-4

Etiology of oncogenic fusions in 5,190 childhood cancers and its clinical and therapeutic implication

Received: 14 April 2022

Accepted: 16 March 2023

Published online: 05 April 2023

Check for updates

Yanling Liu[1], Jonathon Klein[2], Richa Bajpai[2], Li Dong[1], Quang Tran[1], Pandurang Kolekar[1], Jenny L. Smith[3], Rhonda E. Ries[3], Benjamin J. Huang[4], Yi-Cheng Wang[5], Todd A. Alonzo[6], Liqing Tian[1], Heather L. Mulder[1], Timothy I. Shaw[7], Jing Ma[8], Michael P. Walsh[8], Guangchun Song[8], Tamara Westover[8], Robert J. Autry[9,13,14], Alexander M. Gout[1], David A. Wheeler[1], Shibiao Wan[10], Gang Wu[10], Jun J. Yang[9], William E. Evans[9], Mignon Loh[11], John Easton[1], Jinghui Zhang[1], Jeffery M. Klco[8] ✉, Soheil Meshinchi[3] ✉, Patrick A. Brown[12] ✉, Shondra M. Pruett-Miller[2] ✉ & Xiaotu Ma[1] ✉

Oncogenic fusions formed through chromosomal rearrangements are hallmarks of childhood cancer that define cancer subtype, predict outcome, persist through treatment, and can b
mechanistic understanding of the eti
sive. Here we report a comprehensive
pairs by using tumor transcriptome s
cancer patients. We identify diverse f
tein domain, splicing, and gene lengt
fusions. Our mathematical modeling
selection pressure and clinical outco
genic fusions, including *RUNX1-RUNX*
KMT2A-AFDN, with promoter-hijackin
strategies for therapeutic targeting. W
in oncogenic fusions including *KMT2*
NUP98-NSD1, *KMT2A-AFDN* and *ETV6-*
oncogenic fusion gene pairs and den
therapeutic vulnerability for etiology-
general principles on the etiology of
and suggests profound clinical implications including etiology-based risk stratification and genome-editing-based therapeutics.

in oncogenic fusions including *KMT2A-MLLT3*, *KMT2A-MLLT10*, *C11orf95-RELA*, *NUP98-NSD1*, *KMT2A-AFDN* and *ETV6-RUNX1*. We discover neo splice sites in 18 oncogenic fusion gene pairs and demonstrate that such splice sites confer therapeutic vulnerability for etiology-based genome editing. Our study reveals general principles on the etiology of oncogenic fusions in childhood cancer and suggests profound clinical implications including etiology-based risk stratification and genome-editing-based therapeutics.

nature machine intelligence

Perspective

https://doi.org/10.1038/s42256-022-00549-6

Development of metaverse for intelligent healthcare

Received: 14 March 2022

Accepted: 16 September 2022

Published online: 15 November 2022

Check for updates

Ge Wang[1], Andreu Badal[2], Xun Jia[3], Jonathan S. Maltz[4], Klaus Mueller[5], Kyle J. Myers[6], Chuang Niu[1], Michael Vannier[7], Pingkun Yan[1], Zhou Yu[8] & Rongping Zeng[2]

The metaverse integrates physical and virtual realities, enabling humans and their avatars to interact in an environment supported by technologies such as high-speed internet, virtual reality, augmented reality, mixed and extended reality, blockchain, digital twins and artificial intelligence (AI), all enriched by effectively unlimited data. The metaverse recently emerged

https://doi.org/10.1038/s42256-022-00549-6

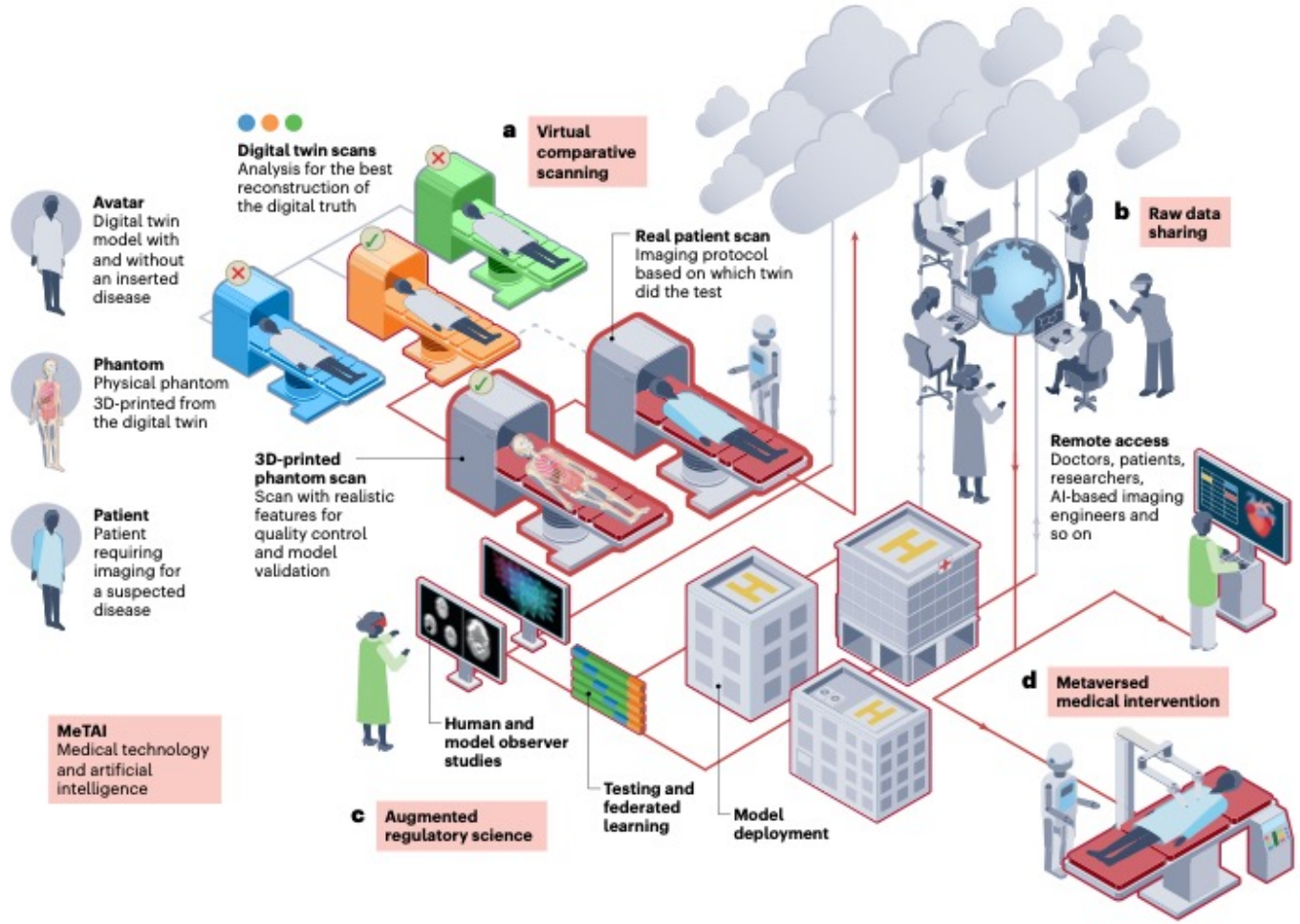

Fig. 1 | MeTAI ecosystem with four major healthcare applications. a, Virtual comparative scanning (to find the best imaging technology in a specific situation). **b**, Raw data sharing (to allow controlled open access to tomographic raw data). **c**, Augmented regulatory science (to extend virtual clinical trials in terms of scope and duration). **d**, 'Metaversed' medical intervention (to perform medical intervention aided by metaverse). In an exemplary implementation of the MeTAI ecosystem, before a patient undergoes a real CT scan, his/her scans are first simulated on various virtual machines to find the best imaging result (**a**). On the basis of this knowledge, a real scan is performed. Then, the metaverse images are transferred to the patient's medical care team, and upon the patient's agreement and under secure computation protocols, the images and tomographic raw data can be made available to researchers (**b**). All these real and simulated images and data as well as other medically relevant information can be integrated in the metaverse and utilized in augmented clinical trials (**c**). Finally, if it is clinically indicated, the patient will undergo a remote robotic surgery aided by the metaverse and followed up in the metaverse for rehabilitation (**d**). Each of the four applications is further described in the main text.

The Oncologist, 2023, **XX**, 1–12
https://doi.org/10.1093/oncolo/oyad005
Advance access publication 24 March 2023
Original Article

OXFORD

Supporting Biomarker-Driven Therapies in Oncology: A Genomic Testing Cost Calculator

Albrecht Stenzinger[*,1], Brian Cuffel[2], Noman Paracha[2], Eric Vail[3], Jesus Garcia-Foncillas[4], Clifford Goodman[5], Ulrik Lassen[6], Gilles Vassal[7], Sean D. Sullivan[8]

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Abstract

Background: Adoption of high-throughput, gene panel-based, next-generation sequencing (NGS) into routine cancer care is widely supported, but hampered by concerns about cost. To inform policies regarding genomic testing strategies, we propose a simple metric, cost per correctly identified patient (CCIP), that compares sequential single-gene testing (SGT) vs. multiplex NGS in different tumor types.

Materials and Methods: A genomic testing cost calculator was developed based on clinically actionable genomic alterations identified in the European Society for Medical Oncology Scale for Clinical Actionability of molecular Targets. Using sensitivity/specificity data for SGTs (immunohistochemistry, polymerase chain reaction, and fluorescence in situ hybridization) and NGS and marker prevalence, the number needed to predict metric was monetarized to estimate CCIP.

Results: At base case, CCIP was lower with NGS than sequential SGT for advanced/metastatic non-squamous non-small cell lung cancer (NSCLC), breast, colorectal, gastric cancers, and cholangiocarcinoma. CCIP with NGS was also favorable for squamous NSCLC, pancreatic, and hepatic cancers, but with overlapping confidence intervals. CCIP favored SGT for prostate cancer. Alternate scenarios using different price estimates for each test showed similar trends, but with incremental changes in the magnitude of difference between NGS and SGT, depending on price estimates for each test.

Conclusions: The cost to correctly identify clinically actionable genomic alterations was lower for NGS than sequential SGT in most cancer types evaluated. Decreasing price estimates for NGS and the rapid expansion of targeted therapies and accompanying biomarkers are anticipated to further support NGS as a preferred diagnostic standard for precision oncology.

Key words: precision oncology; next-generation sequencing; calculator; biomarker.

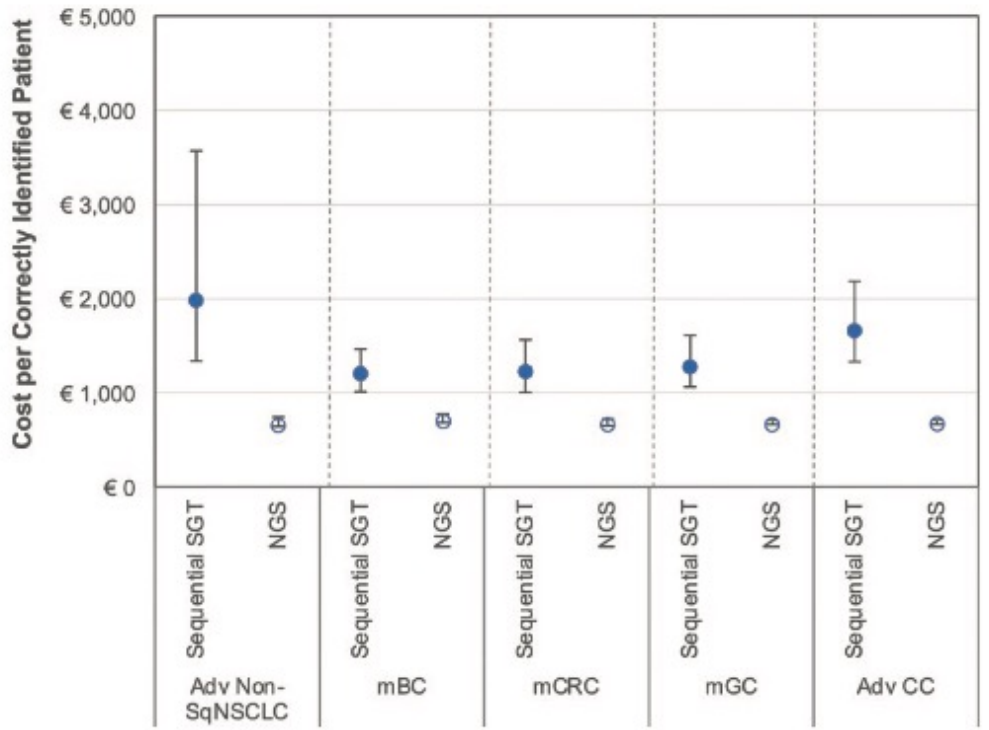

Figure 2. Tumor types favoring next-generation sequencing (NGS) over sequential single gene testing (SGT) in cost per correctly identified patient. Error bars, 95% CI. Adv, advanced; CC, cholangiocarcinoma; mBC, metastatic breast cancer; mCRC, metastatic colorectal carcinoma; mGC, metastatic gastric cancer; sqNSCLC, squamous non–small cell lung cancer.

for this cancer type would become negligible if the diagnostic yield was increased, for example, if both ESCAT 1 and 2 were to be included. When genomic alterations from the ESCAT 2 category are included, the CCIP with NGS further decreases, such that it becomes lower than sequential SGT for advanced prostate cancer (data not shown).

Radiology: Artificial Intelligence

ORIGINAL RESEARCH

External Validation of Deep Learning Algorithms for Radiologic Diagnosis: A Systematic Review

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Received February 25, 2021; revision requested April 5; revision received March 9, 2022; accepted April 12. **Address correspondence to** J.E. (email: *jeng@jhmi.edu*).

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Conflicts of interest are listed at the end of this article.

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Purpose: To assess generalizability of published deep learning (DL) algorithms for radiologic diagnosis.

Materials and Methods: In this systematic review, the PubMed database was searched for peer-reviewed studies of DL algorithms for image-based radiologic diagnosis that included external validation, published from January 1, 2015, through April 1, 2021. Studies using nonimaging features or incorporating non-DL methods for feature extraction or classification were excluded. Two reviewers independently evaluated studies for inclusion, and any discrepancies were resolved by consensus. Internal and external performance measures and pertinent study characteristics were extracted, and relationships among these data were examined using nonparametric statistics.

Results: Eighty-three studies reporting 86 algorithms were included. The vast majority (70 of 86, 81%) reported at least some decrease in external performance compared with internal performance, with nearly half (42 of 86, 49%) reporting at least a modest decrease (≥0.05 on the unit scale) and nearly a quarter (21 of 86, 24%) reporting a substantial decrease (≥0.10 on the unit scale). No study characteristics were found to be associated with the difference between internal and external performance.

Conclusion: Among published external validation studies of DL algorithms for image-based radiologic diagnosis, the vast majority demonstrated diminished algorithm performance on the external dataset, with some reporting a substantial performance decrease.

Supplemental material is available for this article.

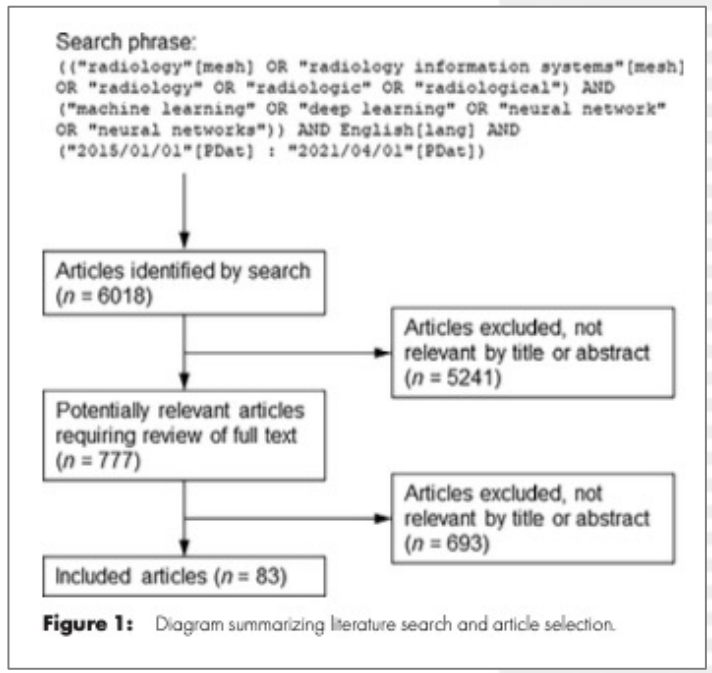


Figure 1: Diagram summarizing literature search and article selection.

Conclusion: Among published external validation studies of DL algorithms for image-based radiologic diagnosis, the vast majority demonstrated diminished algorithm performance on the external dataset, with some reporting a substantial performance decrease.

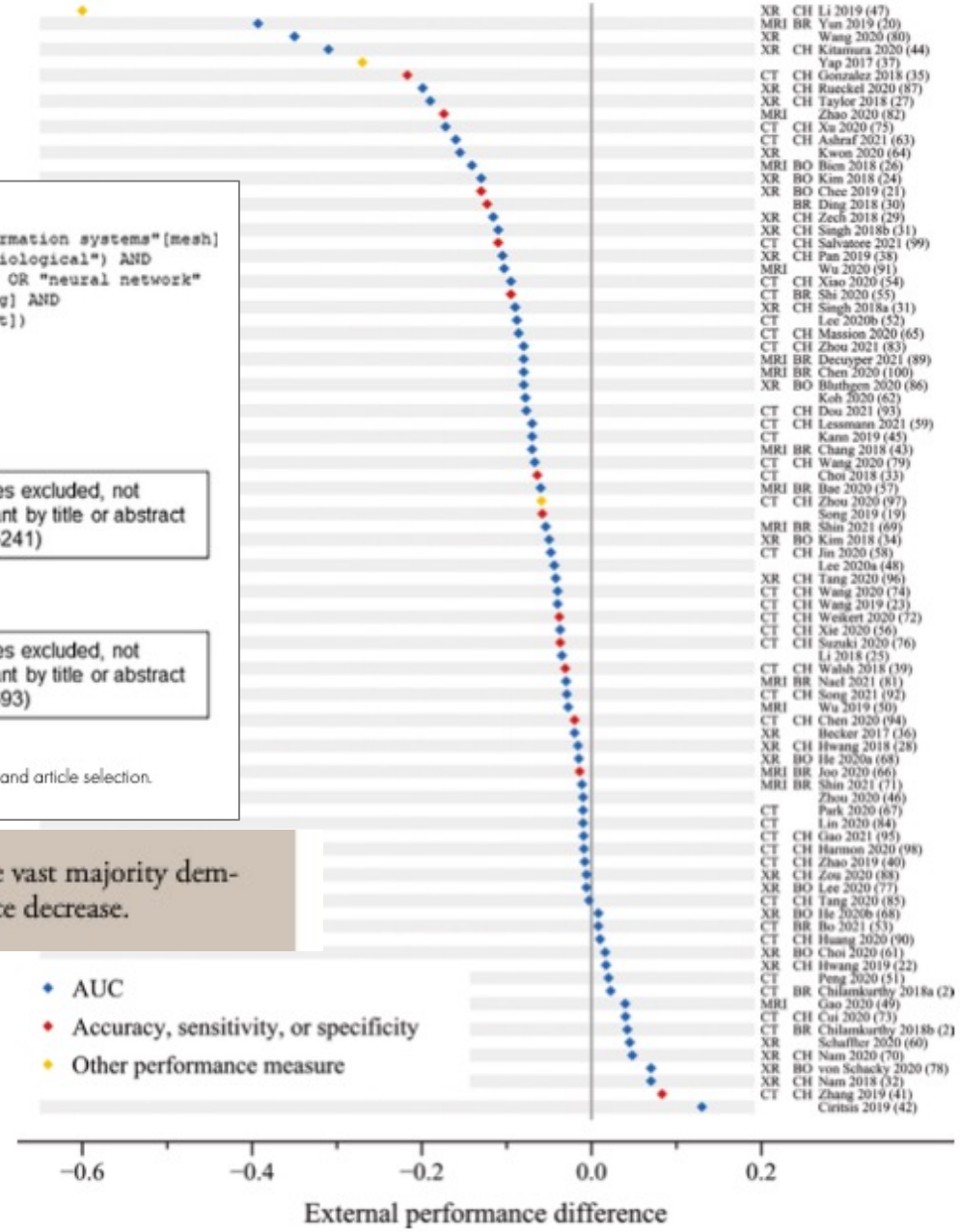


Figure 2: Plot of representative diagnostic performance difference between external and development datasets. The three most common imaging modalities and body parts are indicated. AUC = area under the receiver operating characteristic curve, BO = bone, BR = brain, CH = chest, XR = radiography.

scientific reports

OPEN

Generalization of vision pre-trained models for histopathology

Milad Sikaroudi[1], Maryam Hosseini[1], Ricardo Gonzalez[1,2], Shahryar Rahnamayan[1,3] & H. R. Tizhoosh[1,2,4]✉

Out-of-distribution (OOD) generalization, especially for medical setups, is a key challenge in modern machine learning which has only recently received much attention. We investigate how different convolutional pre-trained models perform on OOD test data—that is data from domains that have not been seen during training—on histopathology repositories attributed to different trial sites. Different trial site repositories, pre-trained models, and image transformations are examined as specific aspects of pre-trained models. A comparison is also performed among models trained entirely from scratch (i.e., without pre-training) and models already pre-trained. The OOD performance of pre-trained models on natural images, i.e., (1) vanilla pre-trained ImageNet, (2) semi-supervised learning (SSL), and (3) semi-weakly-supervised learning (SWSL) models pre-trained on IG-1B-Targeted are examined in this study. In addition, the performance of a histopathology model (i.e., KimiaNet) trained on the most comprehensive histopathology dataset, i.e., TCGA, has also been studied. Although the performance of SSL and SWSL pre-trained models are conducive to better OOD performance in comparison to the vanilla ImageNet pre-trained model, the histopathology pre-trained model is still the best in overall. In terms of top-1 accuracy, we demonstrate that diversifying the images in the training using reasonable image transformations is effective to avoid learning shortcuts when the distribution shift is significant. In addition, XAI techniques—which aim to achieve high-quality human-understandable explanations of AI decisions—are leveraged for further investigations.

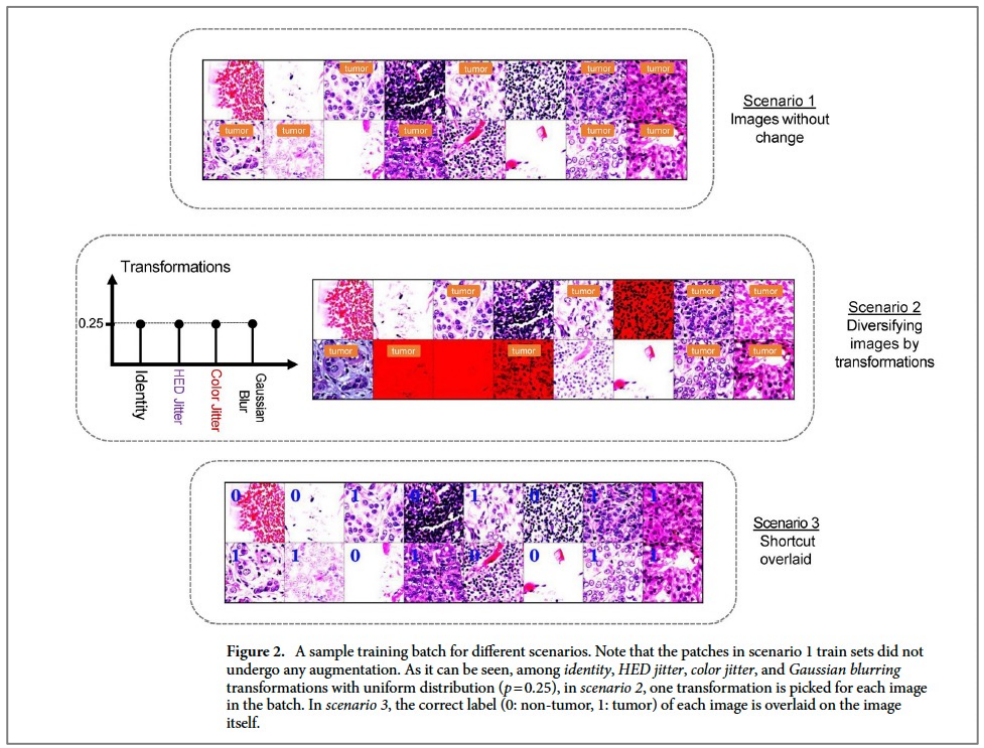


Figure 2. A sample training batch for different scenarios. Note that the patches in scenario 1 train sets did not undergo any augmentation. As it can be seen, among *identity*, *HED jitter*, *color jitter*, and *Gaussian blurring* transformations with uniform distribution ($p=0.25$), in *scenario 2*, one transformation is picked for each image in the batch. In *scenario 3*, the correct label (0: non-tumor, 1: tumor) of each image is overlaid on the image itself.

Events

Next steering committee meeting
5/31 at 3PM ET

1/25/23

PCCP Project

Read More

5/3/2023 noon (ET)

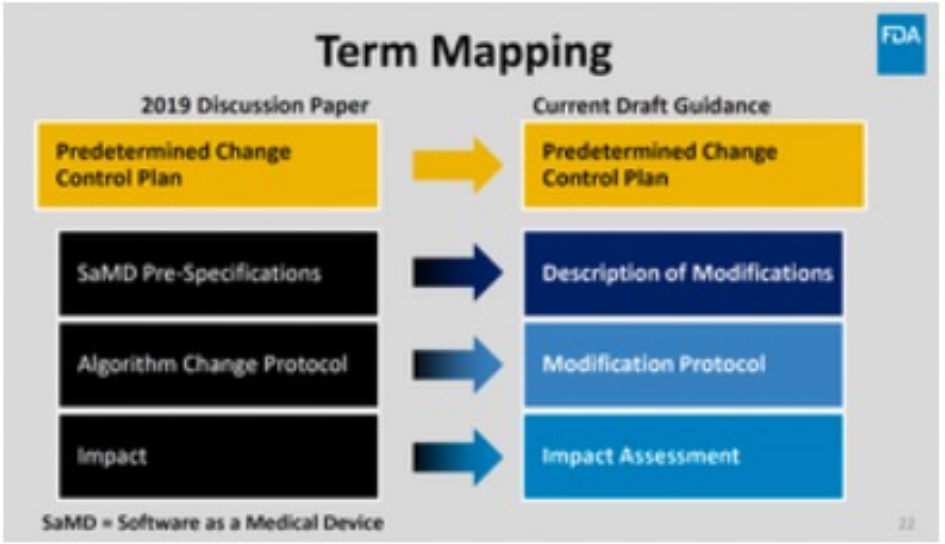
April 13, 2023

FDA hosted a webinar discussing the recently released draft guidance. The webinar provided background on FDA's patient-centered approach, scope of the guidance, modifications for ML-DSFs, and provided examples.

Learn more on FDA website

CDRH Learn

Access additional resources via CDRH Learn, Specialty Technical Topics



Download the slides from the webinar.

1/25/23

HER2-Low Project

Read More

5/12/2023 noon (ET)

HER2-Low Project Session 1

April 7th 2023

In the first scoping meeting, we covered a broad range of relevant topics. The scoping session has resulted in an overview of relevant themes. Watch a recording of the session here.

We ask all project members and PIcc participants to vote for the subtopic that they find most relevant (e.g. for a regulatory science project).

If you have additional publications, resources, or links, please provide those.

Survey: Identify sub-topic of interest

HER2-low meeting ***themes***

Ordering	Specimen (Patient)	Assays	Procedure	Evaluation	Reporting
O1 Change over time	S1 Representativeness	A1 Transition central to **local testing**	P1 Implementation level	E1 **Training**	R1 Standard
O2 Re-testing?	S2 Real-world data	A2 Assay choice	P2 Ref. materials	E2 Image analysis	R2 ASCO CAP
O3 Re-biopsy	S2.1 Data collection **best practices**	A3 FDA-on label vs. LDT	P3 Biology "amount of target"	E3 Pitfalls	
	S2.2 Combination of central & local?		P4 Expression	E4 ONEST	
	S3 Tissue thickness*		P5 Validation (scope)	E5 Heterogeneity	
				E6 Proficiency Testing	
				E7 Adjudication	
				E8 Acceptable range of discordance	
				E9 Competency assessment	

PIcc23
Annual meeting

June 27 & 28

Join us in the Washington DC metro area on Jun 27-28, 2023 for the Pathology Innovation Collaborative Community Annual Meeting. The theme for PIcc23 is "Meet. Synergize. Impact: Unlocking the Potential of Digital Pathology and Artificial Intelligence (AI) through Regulatory Science.

Why you should attend:

- Network with domain experts with keen interest in moving regulatory science forward through in-person interactive working sessions
- The most comprehensive overview from a multistakeholder organization on digital pathology and AI
- Opportunities to share your unique point of view with the entire community
- Synergize to large scale project(s) to create practically relevant regulatory science tools and templates

27-28 JUNE

Networking Dinner Included!

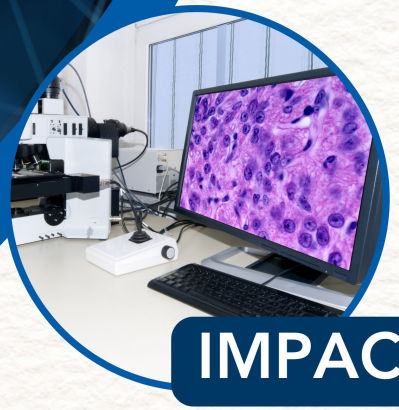
Le Méridien Arlington | 1121 19th St N, Arlington, VA 22209

During PIcc23, thought-leaders, regulators and pioneers in digital pathology will network and discuss:

- Advances in digital pathology and AI applications
- How these advances create new incentives to tackle the next big hurdle, to broadly implement digital pathology and AI/machine learning (ML)
- Impact of regulatory and legislative developments digital pathology and AI tools in diagnostics due to the end of covid pandemic public health emergency
- And more

Visit mdic.tech/PICCMeeting for more information

PICC23: UNLOCKING THE POTENTIAL OF DIGITAL PATHOLOGY AND AI THROUGH REGULATORY SCIENCE



IMPACT

SYNERGIZE

MEET

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Pathology
Innovation
Collaborative
Community

PIcc

Voices of PIcc

A regulatory science community