Pathology Innovation

Collaborative Community

JANUARY UPDATES MEETING

Wednesday

January 25 at 3:00-4:00 PM ET

PIcc2023

Steering committee series: Final Wednesday of every month

Company logos can be added to the homepage with signing of our charter.

Read the charter & learn about the process at https://pathologyinnovationcc.org/collaborative-community-charter

Pathology Innovation Collaborative Community

PIcc

The Alliance for Digital Pathology

A collaborative community with FDA participation

NEW IN 2023:

- Meeting summaries will be posted ahead of monthly update meeting
  - https://pathologyinnovationcc.org/meeting-summaries
- Feel free to reach out with additional information on a topic of interest ahead of meeting
- Come prepared to meeting to discuss topics

FDA

General Updates

GUIDANCE DOCUMENT

REMS Document Technical Conformance Guide

JANUARY 2023

Download the Final Guidance Document

Final

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Issued by: Center for Biologics Evaluation and Research
Center for Drug Evaluation and Research

This Risk Evaluation and Mitigation Strategy (REMS) Document Technical Conformance Guide (Guide) provides updated, detailed instructions on the format of a REMS Document, along with standardized language that describes common REMS requirements for applicants to use whenever possible, to help ensure consistency and facilitate efficient review of the REMS Document. This Guide supports submission of a REMS Document in Structured Product Labeling (SPL) format. In addition, this Guide provides an outline to assist applicants in drafting a Bifurcated REMS Document.

Submit Comments

Submit comments on this guidance document electronically via docket ID: FDA-2013-S-0610 - Specific Electronic Submissions Intended For FDA's Dockets Management Staff (i.e., Citizen Petitions, Draft Proposed Guidance Documents, Variances, and other administrative record submissions)

If unable to submit comments online, please mail written comments to:

Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm 1061

Content current as of:
01/04/2023

Regulated Product(s)
Drugs

Topic(s)
Safety - Issues, Errors, and Problems

Real-World Evidence

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Real-world data (RWD) and real-world evidence (RWE) are playing an increasing role in health care decisions.

- FDA uses RWD and RWE to monitor postmarket safety and adverse events and to make regulatory decisions.
- The health care community is using these data to support coverage decisions and to develop guidelines and decision support tools for use in clinical practice.
- Medical product developers are using RWD and RWE to support clinical trial designs (e.g., large simple trials, pragmatic clinical trials) and observational studies to generate innovative, new treatment approaches.

The 21st Century Cures Act, passed in 2016, places additional focus on the use of these

Content current as of:
12/12/2022

Regulated Product(s)
Biologics
Drugs
Medical Devices
Tobacco

Law(s) & Regulation(s)
21st Century Cures Act of 2016

Novel Drug Approvals for 2022

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Innovative drugs often mean new treatment options for patients and advances in health care for the American public. When it comes the development of new drugs and therapeutic biological products, FDA's Center for Drug Evaluation and Research (CDER) provides clarity to drug developers on the necessary study design elements and other data needed in the drug application to support a full and comprehensive assessment. To do so, CDER relies on its understanding of the science used to create new products, testing and manufacturing procedures, and the diseases and conditions that new products are designed to treat.

Each year, CDER approves a wide range of new drugs and biological products:

- Some of these products have never been used in clinical practice. Below is a listing of new molecular entities and new therapeutic biological products that CDER approved in 2022. This listing does not contain vaccines, allergenic products, blood and blood products, plasma derivatives, cellular and gene therapy products, or other products that the Center for Biologics Evaluation and Research approved in 2022.
- Others are the same as, or related to, previously approved products, and they will compete with those products in the marketplace. See Drugs@FDA for information about all of CDER's approved drugs and biological products.

Advancing Health Through Innovation: New Drug Therapy Approvals 2022
(PDF - 6.8 KB)
Text version

Certain drugs are classified as new molecular entities ("NMEs") for purposes of FDA review. Many of these products contain active moieties that FDA had not previously approved, either as a single ingredient drug or as part of a combination product. These products frequently provide important new therapies for patients. Some drugs are characterized as NMEs for administrative purposes, but nonetheless contain active

Content current as of:
01/10/2023

Regulated Product(s)
Drugs

Updates II

M11 TEMPLATE:

CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL

(CeSHarP)

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page. The draft guidance has been left in the original International Council for Harmonisation format. The final guidance will be reformatted and edited to conform with FDA's good guidance practice regulation and style.

For questions regarding this draft document, contact (CDER) Veronica Pei, 240-402-7091, Veronica.Pei@fda.hhs.gov.

CENTER FOR DRUG EVALUATION AND RESEARCH

What's New in Regulatory Science

FDA

Issue III - 2022

CONTENTS

Brought to you by the Office of Translational Sciences (OTS) in collaboration with the Office of Communications within the Center for Drug Evaluation and Research (CDER)

What's New in Regulatory Science is a quarterly newsletter from the Food and Drug Administration's (FDA's) Center for Drug Evaluation and Research (CDER). It features new developments,

THE OSEL SUMMER RESEARCH PROGRAM PROJECT CATALOG

Summer 2023

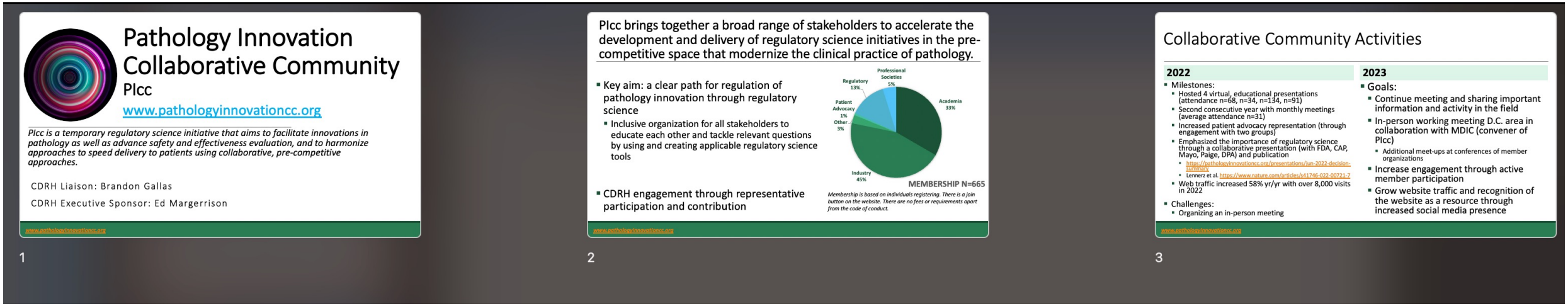
This catalog provides details for the current summer research opportunities offered in OSEL.

FDA U.S. FOOD & DRUG ADMINISTRATION

Office of Science Engineering Laboratories (OSEL)
Center for Devices and Radiological Health (CDRH)
U.S. Food and Drug Administration (FDA)

Presentation to CC SLT

- Brandon Gallas presented on 1/19



LEGISLATIVE UPDATES

In the Senate of the United States,

December 22, 2022.

Resolved, That the bill from the House of Representatives (H.R. 2617) entitled "An Act to amend section 1115 of title 31, United States Code, to amend the description of how performance goals are achieved, and for other purposes.", do pass with the following

SENATE AMENDMENT TO HOUSE AMENDMENT TO SENATE AMENDMENT:

In lieu of the matter proposed to be inserted by the House in Senate amendment 4, insert the following:

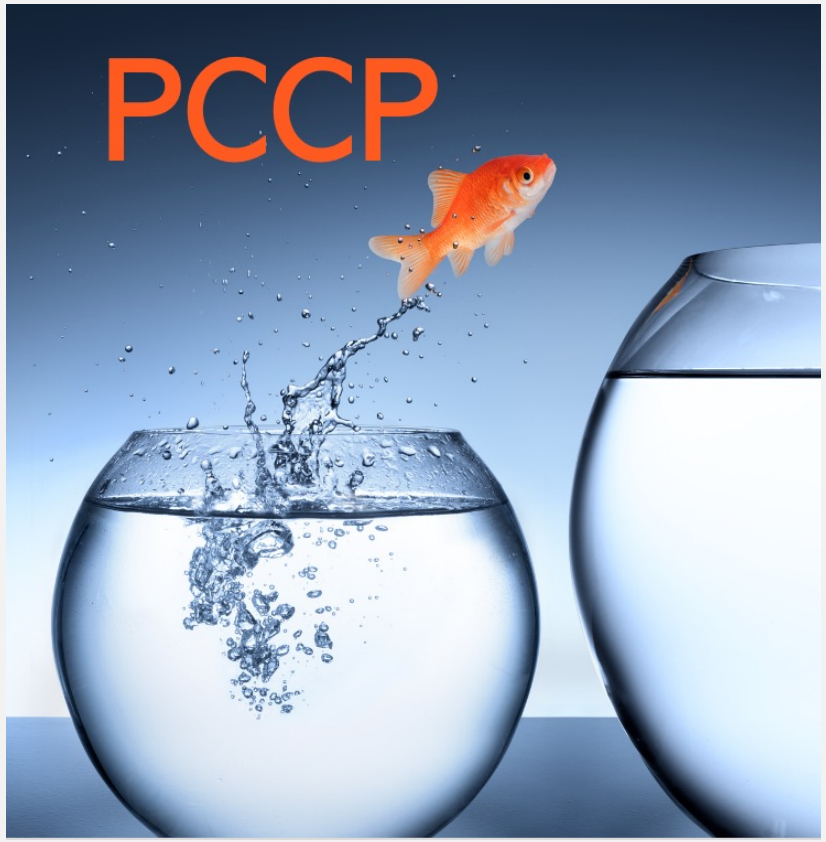
SECTION 1. SHORT TITLE.

CONSOLIDATED APPROPRIATIONS ACT 2023

- **Sec. 3308 Predetermined Change Control Plans for devices:** If a predetermined change control plan is approved or cleared, then a supplemental PMA or a new 510(k) is not required for a change to a device that is consistent with such approved or cleared plan

NEW PROJECTS

PCCP PROJECT



- Highly relevant for developing a proposed regulatory framework - including through issuance of draft guidance on a predetermined change control plan (for software's learning over time);
- We anticipate guidance to follow quickly
- We will host a session/project on Pre-determined Change Control Plan
- Idea is to capture the regulatory implications and review how this PCCP integration came about
- AND
- To be ready and have the relevant context available when the guidance draft comes out = for review and possible commenting

Goldilocks' Project

Exploring the relationship of innovation and regulation

The aim is to create a whitepaper and resource on factors that can help balance regulation and innovation

The concrete aims are

a) To provide a resource online to outline this concept
b) To draft a manuscript for peer-reviewed publication
c) To outline the concept for addition to Wikipedia

We seek participation from all stakeholders interested in the topic
We plan to host 3 open discussion sessions (scoping, outlining, finalization)

HER2 LOW PROJECT

Diagnostic Name (Manufacturer)	Indication - Sample Type	Drug Trade Name (Generic) NDA / BLA	Biomarker(s)	Biomarker(s) (Details)	PMA / 510(k) / 513(f)(2) / HDE (Approval / Clearance / Grant Date)
Bond Oracle HER2 IHC System (Leica Biosystems)	Breast Cancer - Tissue	Herceptin (trastuzumab) BLA 103792	ERBB2 (HER2)	HER-2 protein overexpression	P090015 (04/18/2012)
HercepTest (Dako Denmark A/S)	Breast Cancer - Tissue	Herceptin (trastuzumab) BLA 103792	ERBB2 (HER2)	HER-2 protein overexpression	P980018 (09/25/1998)
HercepTest (Dako Denmark A/S)	Gastric and Gastroesophageal Cancer - Tissue	Herceptin (trastuzumab) BLA 103792	ERBB2 (HER2)	HER-2 protein overexpression	P980018/S010 (10/20/2010)
HercepTest (Dako Denmark A/S)	Breast Cancer - Tissue	Perjeta (pertuzumab) BLA 125409	ERBB2 (HER2)	HER-2 protein overexpression	
HercepTest (Dako Denmark A/S)	Breast Cancer - Tissue	Kadcyla (ado-trastuzumab emtansine) BLA 125427	ERBB2 (HER2)	HER-2 protein overexpression	
InSite Her-2/neu (CB11) Monoclonal Antibody (Biogenex Laboratories, Inc.)	Breast Cancer - Tissue	Herceptin (trastuzumab) BLA 103792	*ERBB2 (HER2)*	HER2protein overexpression	
PATHWAY anti-Her2/neu (4B5) Rabbit Monoclonal Primary Antibody (Ventana Medical Systems, Inc.)	Breast Cancer - Tissue	Herceptin (trastuzumab) BLA 103792	*ERBB2 (HER2)*	HER-2 protein overexpression	
PATHWAY anti-Her2/neu (4B5) Rabbit Monoclonal Primary Antibody (Ventana Medical Systems, Inc.)	Breast Cancer - Tissue	Kadcyla (ado-trastuzumab emtansine) BLA 125427	ERBB2 (HER2)	HER-2 protein overexpression	

Showing 1 to 8 of 8 entries (filtered from 143 total entries)

In this project, we are outlining regulatory aspects of the diagnostic assays and relevant aspects for realization.

Background

Under section 13402(e)(4) of the HITECH Act, breaches of unsecured protected health information affecting 500+ individuals mut be posted by the U.S. Department of Health and Human Services (HHS), Office for Civil Rights

In this project we aim to **examine the data available through the Secretary of HHS** Breach of Unsecure Protected Health Information

The outcome of the project could include

a) An infographics
b) A peer-reviewed publication
c) Several meetings to discuss the findings

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MEDICAL DEVICE INNOVATION CONSORTIUM

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MDIC UPDATES

https://mdic.org/

MDIC Updates

- Cybersecurity Threat-modeling Virtual Bootcamps: 3/13-3/17, 2023

Register for the Next Threat Modeling Bootcamp!

+ Threat Modeling Bootcamp 1: March 13-17

Objectives & discussed topics of the MDIC threat modeling bootcamps:

- Intensive, hands-on sessions on threat modeling.
- Learning about structured, systematic and comprehensive approach to threat modeling for engineering more secure systems from SMEs from public and private sector.
- Learning the latest updates on medical device cybersecurity and related areas from industry representatives.
- Networking opportunity with SMEs from MedTech and non-MedTech sectors to learn on cybersecurity best practices that can be incorporated into the medical device industry.
- The same training that informed the development of the Medical Device Threat Modeling Playbook.

To learn more about the bootcamp along with various other MDIC cybersecurity initiatives, email us at cybersecurity@mdic.org or contact Noor Falah at nfalah@mdic.org or Jithesh Veetil at jveetil@mdic.org

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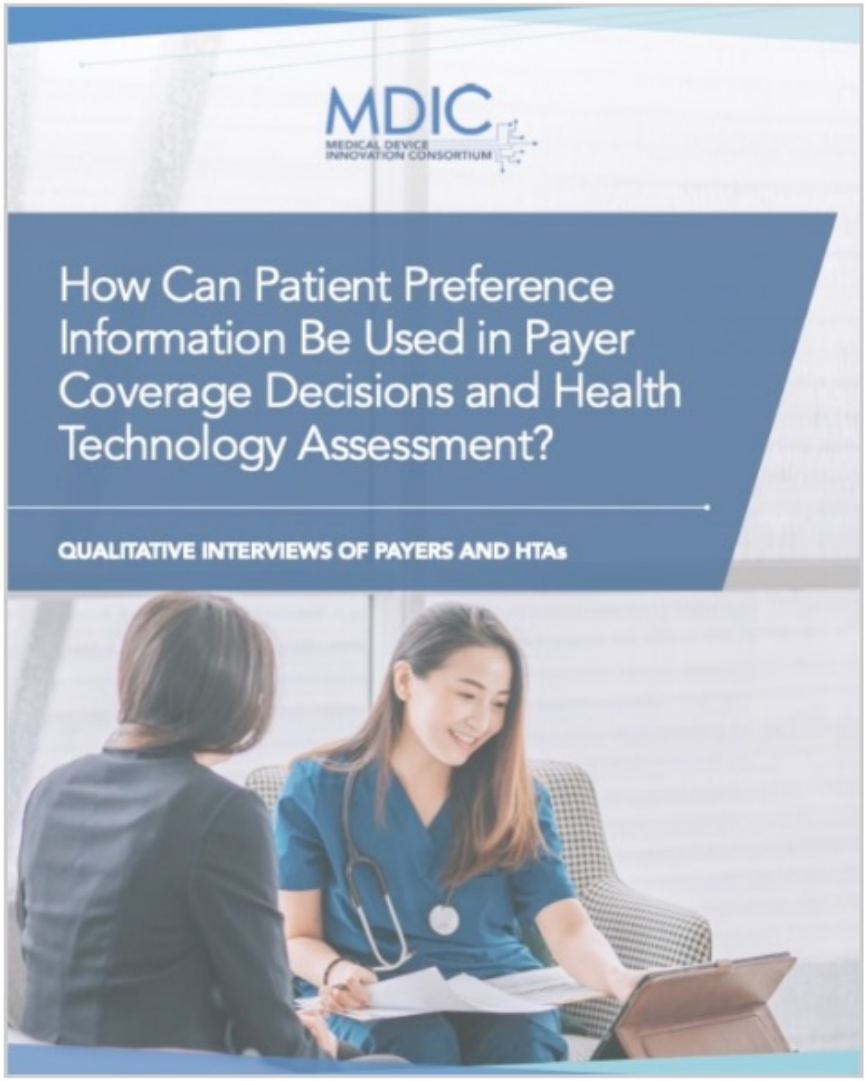
MDIC Updates

- MDIC Publishes White Paper on Using Patient Preference Information for Coverage Decision Making



MDIC Updates

Early Feasibility Studies Best Practices Workshop- February 1, 2023, Boston

Feb 01

Early Feasibility Studies Best Practices Workshop

This workshop is intended to bring together the FDA, CMS, Industry, and clinical site partners to discuss how to implement EFS trials.

By Medical Device Innovation Consortium (MDIC) 239 followers Follow

When and where

Date and time

Wed, February 1, 2023,
1:00 PM – 5:00 PM EST

Location

Omni Boston Hotel at the Seaport 450 Summer Street Boston, MA 02210

Hide map

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MDIC Updates

MDIC Publishes 5G Security Enhancement One Pager

5G Security Enhancements

The *5G Security Enhancements* one-page overview outlines several security enhancements in 5G compared to previous cellular communication technologies while highlighting security configurations and scalable security solutions / protections.

This one-page overview accompanies the *Landscape Analysis of 5G in Healthcare*. Learn more about MDIC's 5G-Enabled Health Technologies. Read the press release.

Contact

Contact us at 5G@mdic.org or reach out the MDIC program staff:

- Jithesh Veetil, PhD, Senior Program Director (Digital Health & Technology) jveetil@mdic.org
- Jennifer Waters, Project Manager, jwaters@mdic.org

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MDIC Updates

Call for Volunteers! MDIC Digital Health Software Vertical

The MDIC Digital Health Software Vertical is looking for software experts with experience in deploying software in various formats like: embedded in medical device/diagnostics, mobile apps, and desktop apps, among others. We also seek more regulatory experts who have experience with Class III software submissions to participate in these activities. Selected volunteers work with abrader group to develop an MDIC framework

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MDIC Updates

- MDIC Publishes First Landscape Analysis of 5G in Healthcare

- Please contact Noor Falah nfalah@mdic.org or Jithesh Veetil jveetil@mdic.org with any questions about MDIC initiatives

In-person meeting

- D.C. Area
- Timeline?
- Re-cap of key stakeholders (e.g., MDIC, DPA and DPA Foundation, CAP, ASCP, FOCR, patient advocacy, industry, FDA, NIH, CDC, ACR, PCORI – broad membership, workgroups)

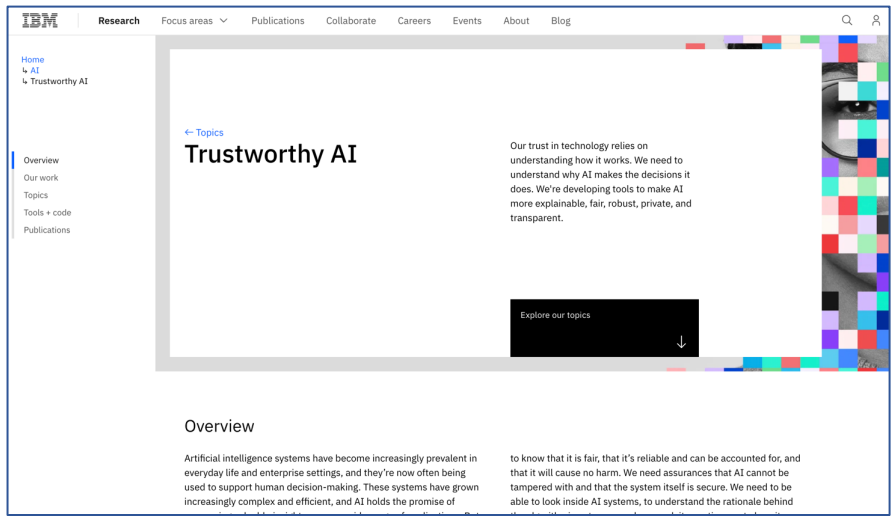
- **Aim:** provide an in-person event of activities and derive key questions
- Inclusion of FDA personnel


World Health
Organization

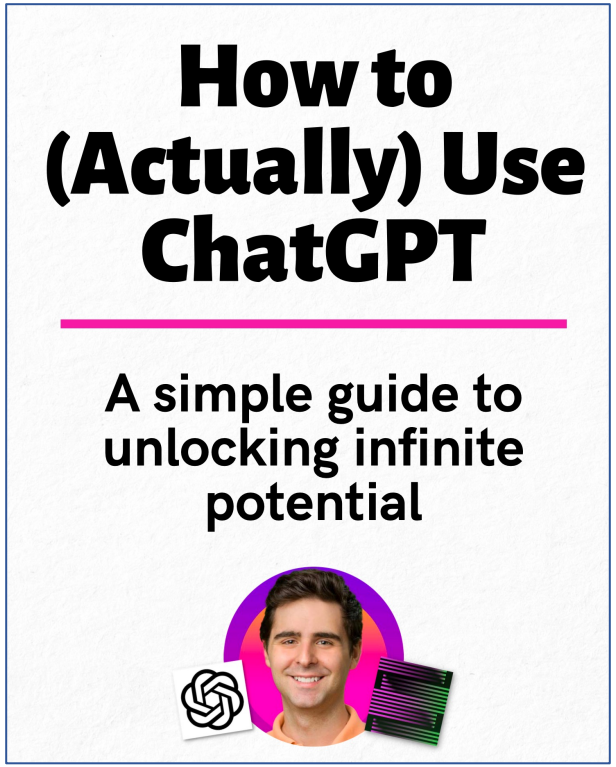
Mapping the Evidence for the World Health Organization (WHO) Classification of Tumours: a Living Evidence Gap Map by Tumour Type (WCT EVI MAP)

- €3.5 million from the European Commission
- 4-year project
- in collaboration with six other international institutions

Resources 1, 2, 3



IBM Trustworthy AI



AN FDA FOR ALGORITHMS

ANDREW TUTT*

The rise of increasingly complex algorithms calls for critical thought about how best to prevent, deter, and compensate for the harms that they cause. This Article argues that the criminal law and tort regulatory systems will prove no match for the difficult regulatory puzzles algorithms pose. Algorithmic regulation will require federal uniformity, expert judgment, political independence, and pre-market review to prevent—without stifling innovation—the introduction of unacceptably dangerous algorithms into the market. This Article proposes that certain classes of new algorithms should not be permitted to be distributed or sold without approval from a government agency designed along the lines of the FDA. This "FDA for Algorithms" would approve certain complex and dangerous algorithms when it could be shown that they would be safe and effective for their intended use and that satisfactory measures would be taken to prevent their harmful misuse. Lastly, this Article proposes that the agency should serve as a centralized expert regulator that develops guidance, standards, and expertise in partnership with industry to strike a balance between innovation and safety.

TABLE OF CONTENTS

* Attorney-Adviser, Office of Legal Counsel, Department of Justice. The views expressed in this essay are the author's only and do not necessarily reflect the views of the Department of Justice or the Office of Legal Counsel. The author wishes to thank the participants in the 2016 "Unlocking the Black Box" conference at Yale Law School. Special thanks are owed to Jack Balkin, Frank Pasquale, and Jonathan Manes. The author also wishes to thank the editors of the *Administrative Law Review*, especially Ross Handler and Kimberly Koruba, for their dogged editing and inexhaustible patience.

Papers

Perspective

CLINICAL TRIALS

Clinical Trials
1–10

DOI: 10.1177/17407745221147689
journals.sagepub.com/home/ctj
SAGE

Now is the time to fix the evidence generation system

Robert M Califf

Abstract

Despite enormous advances in biomedical science, corresponding improvements in health outcomes lag significantly. This is particularly true in the United States, where life expectancy trails far behind that of other high-income countries. In addition, substantial disparities in life expectancy and other health outcomes exist as a function of race, ethnicity,

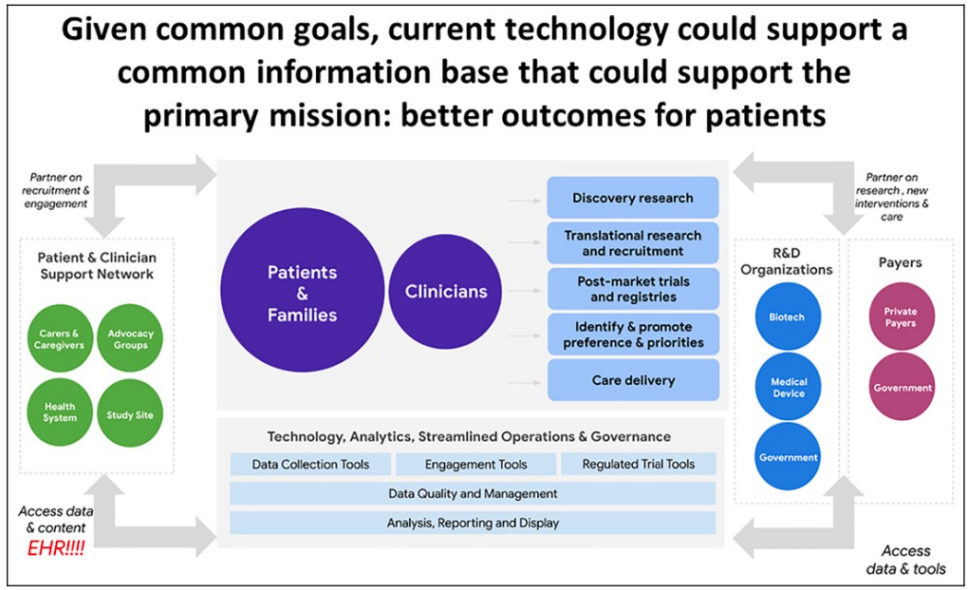
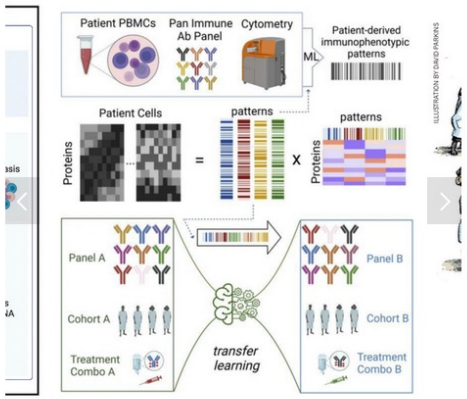


Figure 2. Possible configuration of components and activities needed to overcome systemic fragmentation and create a highly functional healthcare delivery system and clinical research enterprise.
Source: Figure adapted with permission from Califf.[30]

Papers ...>50

Papers



- Romanchikova et al. The need for measurement science in digital pathology (link)
- López-Otín et al. Hallmarks of aging: An expanding universe (link) (download PDF)
- Wendell A. Lim. The emerging era of cell engineering: Harnessing the modularity of cells to program complex biological function (link) (download PDF)
- Yang et al. Loss of epigenetic information as a cause of mammalian aging (download PDF)
- Etienne-Grimaldi. Current diagnostic and clinical issues of screening for dihydropyrimidine dehydrogenase deficiency (download PDF)
- Clinton et al. Genomic heterogeneity as a barrier to precision oncology in urothelial cancer (download PDF)
- Gichoya et al. AI recognition of patient race in medical imaging: a modelling study (download PDF)
- Riciti et al. Clinical Validation of Artificial Intelligence–Augmented Pathology Diagnosis Demonstrates Significant Gains in Diagnostic Accuracy in Prostate Cancer Detection (download PDF)
- Hind et al. Experiences with Improving the Transparency of AI Models and Services (download PDF)
- Kung et al. Performance of ChatGPT on USMLE: Potential for AI-Assisted Medical 2 Education Using Large Language Models (download PDF)
- Sidiropoulos et al. Integrated T cell cytometry metrics for immune-monitoring applications in immunotherapy clinical trials (download PDF)
- Horgan et al. The gaps between the new EU legislation on in vitro diagnostics and the on-the-ground reality (download PDF)
- Reddi et al. Nondestructive 3D Pathology Image Atlas of Barrett Esophagus With Open-Top Light-Sheet Microscopy (download PDF)
- Gao et al. Application of Machine Learning in Intelligent Medical Image Diagnosis and Construction of Intelligent Service Process (download PDF)
- Perez et al. Ex vivo 3D scanning and specimen mapping in anatomic pathology (download PDF)
- Otaki et al. Investigating the evolution of undergraduate medical students' perception and performance in relation to an innovative curriculum-based research module: A convergent mixed methods study launching the 8A-Model (download PDF)
- Wu et al. All HER2-negative breast cancer patients need gBRCA testing: cost-effectiveness and clinical benefits (download PDF)
- de Baca et al. Ordo ab Chao Framework for an Integrated Disease Report (download PDF)
- Bartoletti et al. Number Needed to Treat in Trials of Targeted Therapies for Advanced Ovarian Cancer (download PDF)
- Wang et al. Optical ptychography for biomedical imaging: recent progress and future directions [Invited] (download PDF)
- Siegel et al. Cancer statistics, 2023 (download PDF)
- Castaneda et al. Mechanisms of cancer metastasis (download PDF)
- Mario Plebani. Quality Indicators to Detect Pre-Analytical Errors in Laboratory Testing (download PDF)
- Ioannidis, Klavans, & Kevin W. Boyack. The scientists who publish a paper every five days (download PDF)
- Mark D. Stewart & Valsamo Anagnostou. Liquid biopsies coming of age: biology, emerging technologies, and clinical translation- An introduction to the JITC expert opinion special review series on liquid biopsies (download PDF)
- Marston et al. A polygenic risk score predicts atrial fibrillation in cardiovascular disease (download PDF)
- Agrawal et al. Use of Single-Arm Trials for US Food and Drug Administration Drug Approval in Oncology, 2002-2021 (download PDF)
- Kadri Altundag. Triple-Negative Receptor Conversion at Metastatic Sites Might Show Better Efficacy in Patients Who Received Sacituzumab Govitecan (download PDF)
- Cima et al. Decline of case reports in pathology and their renewal in the digital age: an analysis of publication trends over four decades (download PDF)
- Light et al. Germline TP53 mutations undergo copy number gain years prior to tumor diagnosis (download PDF)
- McGenity et al. Survey of liver pathologists to assess attitudes towards digital pathology and artificial intelligence (download PDF)
- Brazel et al. Genomic Alterations and Tumor Mutation Burden in Merkel Cell Carcinoma (download PDF)
- Shah, Rooke-Ley, & Brown. Corporate Investors in Primary Care — Profits, Progress, and Pitfalls (download PDF)
- Bates et al. The Safety of Inpatient Health Care (download PDF)
- Park, Leahy, & Funk. Papers and patents are becoming less disruptive over time (download PDF)
- Parwani et al. An update on computational pathology tools for genitourinary pathology practice: A review paper from the Genitourinary Pathology Society (GUPS) (download PDF)
- Valstar et al. The tubarial salivary glands: A potential new organ at risk for radiotherapy (download PDF)
- Heidari et al. Sex and Gender Equity in Research: rationale for the SAGER guidelines and recommended use (download PDF)
- Osinski et al. Artificial intelligence-augmented histopathologic review using image analysis to optimize DNA yield from formalin-fixed paraffin-embedded slides (download PDF)
- Gerasimavicius, Livesey, & Marsh. Loss-of-function, gain-of-function and dominant- negative mutations have profoundly different effects on protein structure (download PDF)
- Davis et al. Long COVID: major findings, mechanisms and recommendations (download PDF)
- Mattick et al. Long non-coding RNAs: definitions, functions, challenges and recommendations (download PDF)
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- Summary of Zhang et al. Machine learning identifies long COVID patterns from electronic health records (download PDF)
- Vivek Subbiah. The next generation of evidence-based medicine (download PDF)
- Soenksen et al. Integrated multimodal artificial intelligence framework for healthcare applications (download PDF)
- Classen, Longhurst, & Thomas. Bending the patient safety curve: how much can AI help? (download PDF)
- Greenberg et al. Automatic gradian cell detection for improving the efficacy and accuracy of hirschprung disease diagnosis (download PDF)
- Stein et al. SARS-CoV-2 infection and persistence in the human body and brain at autopsy (link)
- Stockley et al. A Canadian Ring Study to Optimize Detection of NTRK Gene Fusions by Next-Generation RNA Sequencing (download PDF)
- Vikas et al. Mismatch Repair and Microsatellite Instability Testing for Immune Checkpoint Inhibitor Therapy: ASCO Endorsement of College of American Pathologists Guideline (download PDF)
- Villani et al. The clinical utility of integrative genomics in childhood cancer extends beyond targetable mutations (download PDF)
- Wu et al. Graph deep learning for the characterization of tumour microenvironments from spatial protein profiles in tissue specimens (download PDF)
- Lin et al. Multiplexed 3D atlas of state transitions and immune interaction in colorectal cancer (download PDF) (link)
- Mayer et al. A tissue atlas of ulcerative colitis revealing evidence of sex-dependent differences in disease-driving inflammatory cell types and resistance to TNF inhibitor therapy (download PDF)
- Vink et al. All is nice and well unless she outshines him: Higher social status benefits women's well-being and relationship quality but not if they surpass their male partner (download PDF)
- Dorgham Khatib & Genela Morris. Dual role for dopamine in shaping spontaneity (download PDF)

Events

- February 7 - NHS Pathology Conference North 2023 | Manchester, UK
- February 2-16 (3 Sessions) - Free Webinar Series About Histosuite Tools
- February 27 - Public meeting: FDA Rare Disease Day 2023
- March 6-7 - Cambridge Healthtech Institute's 3rd Annual Digital Medicine The Next Frontier in Precision Medicine | San Diego, CA, USA
- March 11 - 2023 ADASP Annual Meeting | New Orleans, LA, USA
- March 11-16 - USCAP Annual Meeting: Facing the Unknown | New Orleans, LA, USA
- June 14-17 - 19th European Congress on Digital Pathology (ECDP 2023) | Catania, Italy

See you next month