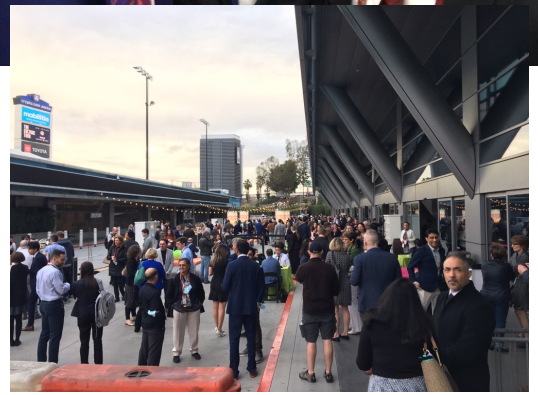
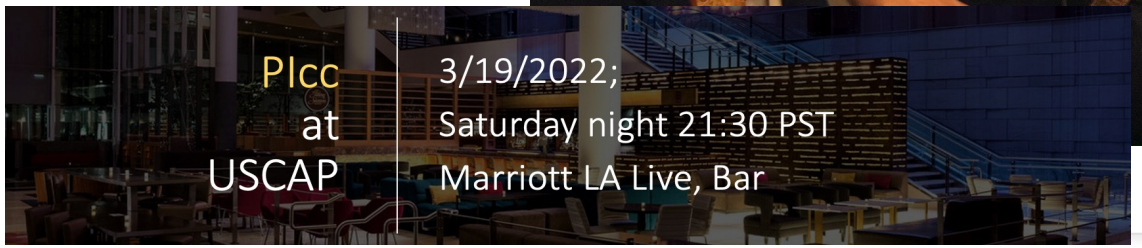
Monthly Steering Committee Meetings

March 30 2022 3-4PM ET

Pathology Innovation Collaborative Community

PIcc at USCAP





Update:
Unique Patient Identifier

117TH CONGRESS
1ST SESSION

S. _____

To amend title XI of the Social Security Act to repeal the requirement for unique health identifiers.

IN THE SENATE OF THE UNITED STATES

Mr. PAUL (for himself and Mrs. BLACKBURN) introduced the following bill; which was read twice and referred to the Committee on

A BILL

To amend title XI of the Social Security Act to repeal the requirement for unique health identifiers.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the "National Patient ID Repeal Act".

SEC. 2. REPEAL OF REQUIREMENT FOR UNIQUE HEALTH IDENTIFIERS.

Section 1173(b) of the Social Security Act (42 U.S.C. 1320d–2(b)) is repealed.

COMMITTEE *on* APPROPRIATIONS
CHAIRMAN PATRICK LEAHY

For Immediate Release:
October 18, 2021

Contact:
Jay Tilton : (202) 224-2667
Senator Murray's Press Office: Helen Hare (202) 224-2834

SUMMARY
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES
FISCAL YEAR 2022 APPROPRIATIONS BILL

Washington, D.C. – The fiscal year 2022 Labor/HHS/Education appropriations bill includes $220.8 billion in base non-defense discretionary funding, an increase of $46.7 billion over the comparable fiscal year 2021 level, and $5.8 billion less than the budget request. In addition, the bill includes $2.1 billion in allocation adjustments for preventing waste, fraud, abuse, and improper payments, a $243 million increase over the fiscal year 2021 level, and the same as the President's budget request.

U.S. Senator Patty Murray (D-WA.), Chair of the Labor, Health and Human Services, Education, and Related Agencies Subcommittee said:

"I believe strongly that now more than ever, our focus needs to be on ensuring our country can come back better from the COVID-19 pandemic. I'm proud that this bill dramatically increases funding for our public schools and Pell grants to put higher education within reach for more students, and that it would strengthen our public health infrastructure so that we are better prepared for the next pandemic as well as ongoing public health crises like substance use disorders and mental health. Our bill also makes historic investments in maternal and reproductive health, specifically through the Title X family planning program and efforts to fix our country's unacceptable maternal mortality crisis, while removing the Hyde and Weldon amendments that for too long have interfered with millions of peoples' ability to exercise their constitutional right to abortion.

"As I've always said, budgets are a statement of your values and priorities—and I believe the investments in this bill are investments in a stronger, fairer future for all our country's kids, workers, families and communities."

Key Points & Highlights

Public Health and Preparedness: As a nation, we were unprepared for the COVID-19 pandemic. Decades of underinvestment in public health infrastructure and erosion of the public health workforce contributed to the pandemic's heavy toll. To ensure we are prepared for the

Public Law 111–148
111th Congress

An Act

Entitled The Patient Protection and Affordable Care Act.

Mar. 23, 2010
[H.R. 3590]

Patient Protection and Affordable Care Act.
42 USC 18001 note.

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Patient Protection and Affordable Care Act".

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

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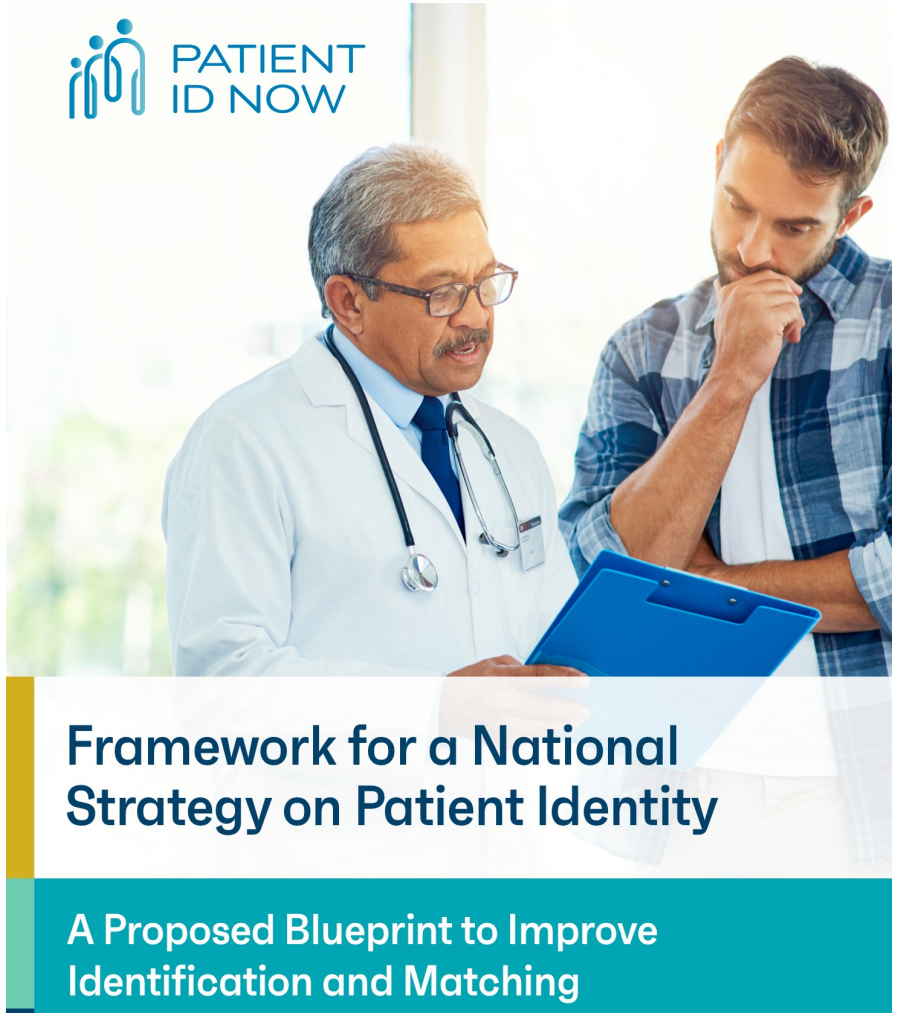
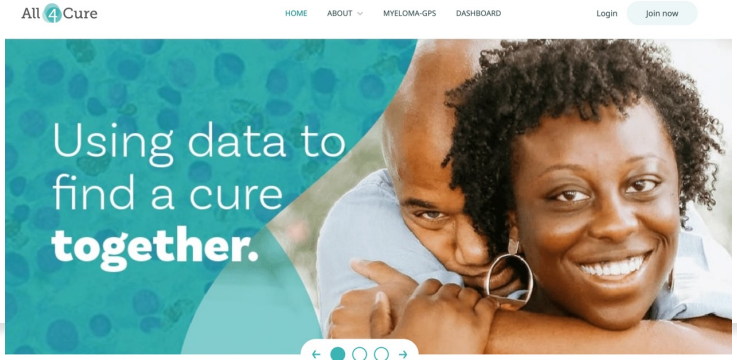


Patient Advocacy

- APPIA:
  - Attended board meeting at USCAP and presented project proposal

Patient Advocacy



OPINION

Check for updates

1 Department of Clinical Science, Kaiser Permanente Bernard J. Tyson School of Medicine

2 ExPPect

3 Society to Improve Diagnosis in Medicine

Cite this as: *BMJ* 2022;376:o451
http://dx.doi.org/10.1136/bmj.o451
Published: 22 February 2022

Thanking patients for their role in research is part of creating wider cultural change

Acknowledging the participants who make research possible recognises their humanity and contributions to medical care, say Michael H Kanter and Suzanne Schrandt

Michael H Kanter,[1] Suzanne Schrandt[2,3]

Our ability to rapidly create new knowledge about covid-19 was only possible because of the many patients whose medical data were mined for research purposes and others who lined up to participate in clinical trials. Medical science cannot advance without such patients, but they are rarely even acknowledged in publications. These omissions are indicators of a medical and research culture that does not always solicit or consider patients' experiences as much as it should. We believe, however, that a greater recognition of patients' contribution to research would help to create a cultural shift in how patients are involved in research, leading to benefits for all.

A thankless experience

In 1973, one of us (MHK) was diagnosed with metastatic testicular carcinoma. His medical data

artificial intelligence and big data analytics to retrospective data.[1] Although this trend has raised substantial concerns and discussion about patient privacy, possible exploitation, and ways for patients to directly benefit from the use of their data, acknowledging patient contributions in any resulting publications has received less attention.

Researchers usually receive compensation for the time they've spent conducting studies and credit for their publications as listed authors, which can advance their careers. Patient participants in studies receive none of these benefits. Indeed, for patients included in medical records research, for example, they are often unaware of its existence or their participation and thus unable to even take pleasure in knowing they have helped others or contributed to scientific knowledge.

original reports abstract

PRECISION MEDICINE

Safety, Feasibility, and Merits of Longitudinal Molecular Testing of Multiple Metastatic Sites to Inform mTNBC Patient Treatment in the Intensive Trial of Omics in Cancer

Kimberly A. Burton, PhD[1,2,3,4]; Elisabeth Mahen, BS[2,5,6]; Eric Quentin Konnick, MD, MS[7]; Sibel Blau, MD[2,3]; Michael O. Dorschner, PhD[8,9,10]; Arturo B. Ramirez, PhD[11]; Stephen C. Schmechel, MD[8]; Chaozhong Song, PhD[2,5,6]; Rahul Parulkar, PhD[12]; Stephanie Parker, BA[3,4]; Francis Mark Senecal, MD[3,4]; Colin C. Pritchard, MD, PhD[7]; Brigham H. Mecham, PhD[13]; Christopher Szeto, PhD[12]; Patricia Spilman, MA[14]; Jingchun Zhu, PhD[15]; Vijayakrishna K. Gadi, MD, PhD[16,17]; Roy Ronen, PhD[18]; Jackie Stilwell, PhD[11]; Eric Kaldjian, MD[11]; Janusz Dutkowski, PhD[18]; Stephen Charles Benz, PhD[12]; Shahrooz Rabizadeh, PhD[14]; Patrick Soon-Shiong, MD[12,14]; and C. Anthony Blau, MD[2,5,6,19]

PURPOSE Patients with metastatic triple-negative breast cancer (mTNBC) have poor outcomes. The Intensive Trial of Omics in Cancer (ITOMIC) sought to determine the feasibility and potential efficacy of informing treatment decisions through multiple biopsies of mTNBC deposits longitudinally over time, accompanied by analysis using a distributed network of experts.

METHODS Thirty-one subjects were enrolled and 432 postenrollment biopsies performed (clinical and study-directed) of which 332 were study-directed. Molecular profiling included whole-genome sequencing or whole-exome sequencing, cancer-associated gene panel sequencing, RNA-sequencing, and immunohistochemistry. To afford time for analysis, subjects were initially treated with cisplatin (19 subjects), or another treatment they had not received previously. The results were discussed at a multi-institutional ITOMIC Tumor Board, and a report transmitted to the subject's oncologist who arrived at the final treatment decision in conjunction with the subject. Assistance was provided to access treatments that were predicted to be effective.

RESULTS Multiple biopsies in single settings and over time were safe, and comprehensive analysis was feasible. Two subjects were found to have lung cancer, one had carcinoma of unknown primary site, tumor samples from three subjects were estrogen receptor–positive and from two others, human epidermal growth factor receptor 2–positive. Two subjects withdrew. Thirty-four of 112 recommended treatments were accessed using approved drugs, clinical trials, and single-patient investigational new drugs. After excluding the three subjects with nonbreast cancers and the two subjects who withdrew, 22 of 26 subjects (84.6%) received at least one ITOMIC Tumor Board–recommended treatment.

CONCLUSION Further exploration of this approach in patients with mTNBC is merited.

Telehealth

- Fact sheet released by White House
- Post-COVID Priorities for Medicare Telehealth Reform group letter

Good Machine Learning Practice for Medical Device Development

U.S. FOOD & DRUG ADMINISTRATION | Health Canada Santé Canada | Medicines & Healthcare products Regulatory Agency

Good Machine Learning Practice for Medical Device Development: Guiding Principles

October 2021

The U.S. Food and Drug Administration (FDA), Health Canada, and the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) have jointly identified 10 guiding principles that can inform the development of Good Machine Learning Practice (GMLP). These guiding principles will help promote safe, effective, and high-quality medical devices that use artificial intelligence and machine learning (AI/ML).

Artificial intelligence and machine learning technologies have the potential to transform health care by deriving new and important insights from the vast amount of data generated during the delivery of health care every day. They use software algorithms to learn from real-world use and in some situations may use this information to improve the product's performance. But they also present unique considerations due to their complexity and the iterative and data-driven nature of their development.

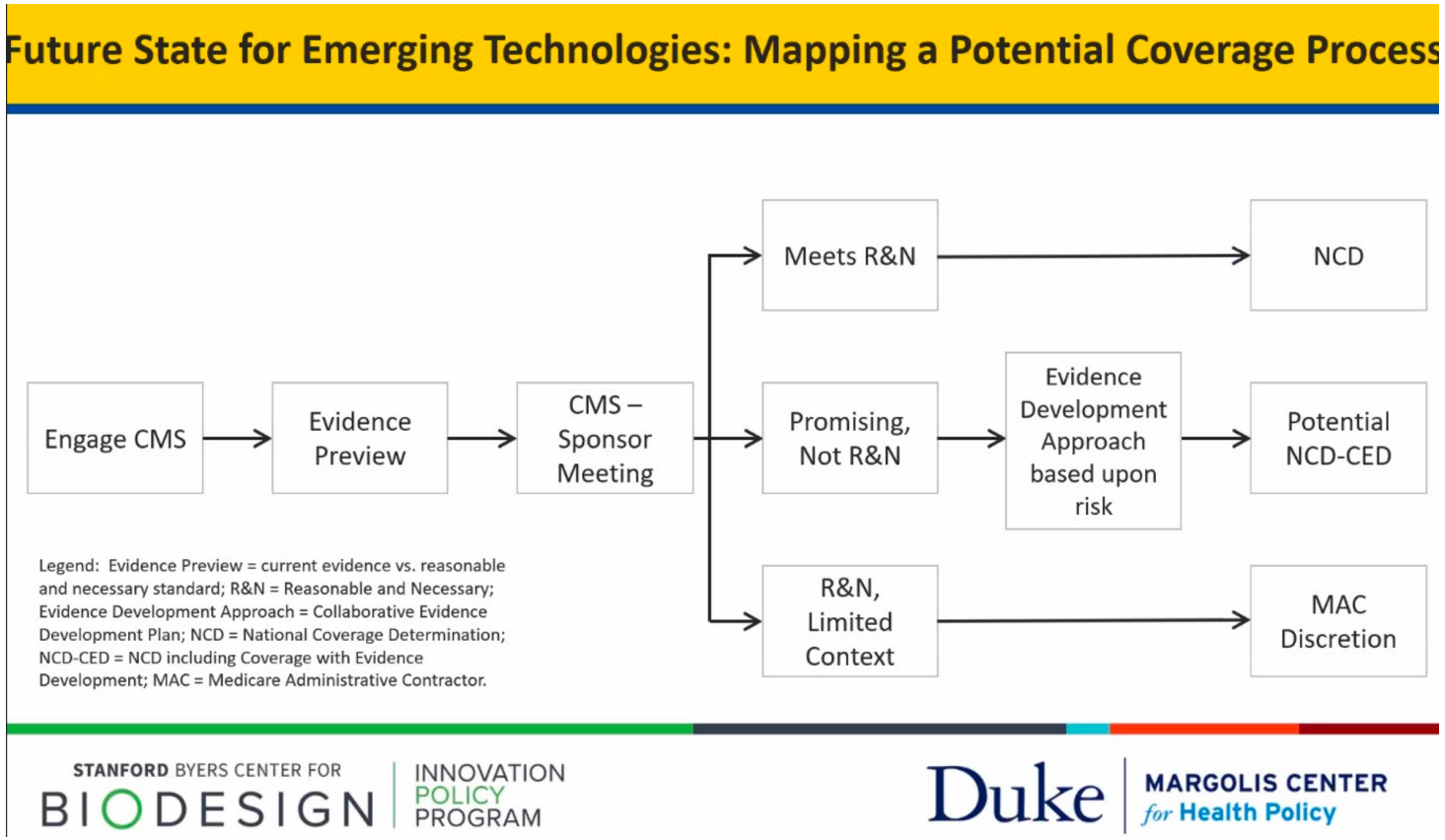
These 10 guiding principles are intended to lay the foundation for developing Good Machine Learning Practice that addresses the unique nature of these products. They will also help cultivate future growth in this rapidly progressing field.

The 10 guiding principles identify areas where the

Good Machine Learning Practice for Medical Device Development: Guiding Principles	
Multi-Disciplinary Expertise Is Leveraged Throughout the Total Product Life Cycle	Good Software Engineering and Security Practices Are Implemented
Clinical Study Participants and Data Sets Are Representative of the Intended Patient Population	Training Data Sets Are Independent of Test Sets
Selected Reference Datasets Are Based Upon Best Available Methods	Model Design Is Tailored to the Available Data and Reflects the Intended Use of the Device
Focus Is Placed on the Performance of the Human-AI Team	Testing Demonstrates Device Performance During Clinically Relevant Conditions
Users Are Provided Clear, Essential Information	Deployed Models Are Monitored for Performance and Re-training Risks are Managed

- GMLP open for comment through FDA docket FDA-2019-N-1185
- Example: Comment from Intel

Transitional Coverage for Emerging Technologies



- Transcript & recording from March 28th webinar available
- Ruggles et al. The Need for Accelerated Medicare Coverage of Innovative Technologies: Impact on Patient Access and the Innovation Ecosystem

Featured papers

Couture et al. Image analysis with deep learning to predict breast cancer grade, ER status, histologic subtype, and intrinsic subtype

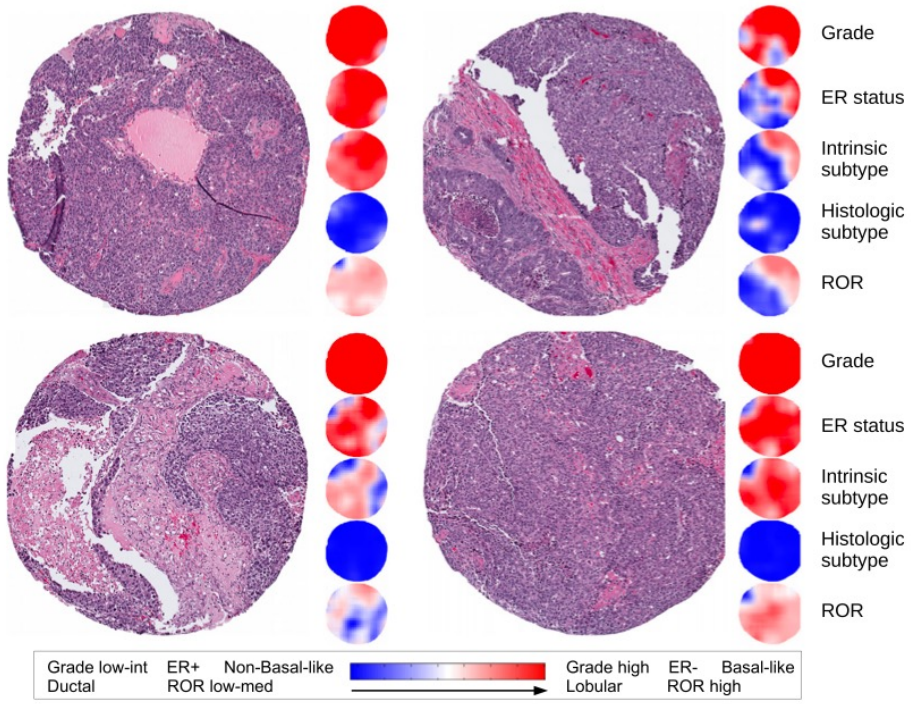


Fig. 2 Four H&E cores from a single patient and heat maps indicating the class predictions over different regions of the image. Class probabilities are indicated by the intensity of red/blue color with greater intensity for higher probabilities. Uncertainty in the prediction is indicated by white. This patient was labeled as high grade, ER negative, Basal-like intrinsic subtype, ductal histologic subtype, and high ROR

Revie et al. Current problems and perspectives on colour in medical imaging

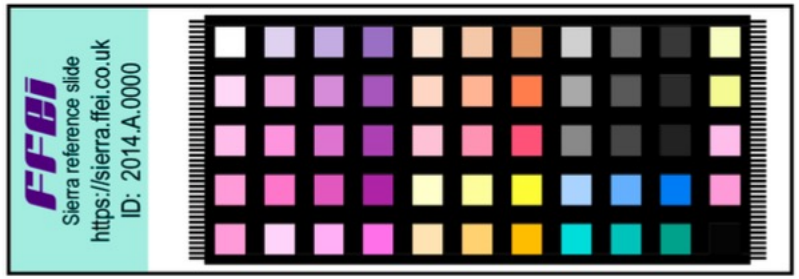


Figure 1 Sierra calibration slide

Bergstrom et al. Mapping clustered mutations in cancer reveals APOBEC3 mutagenesis of ecDNA

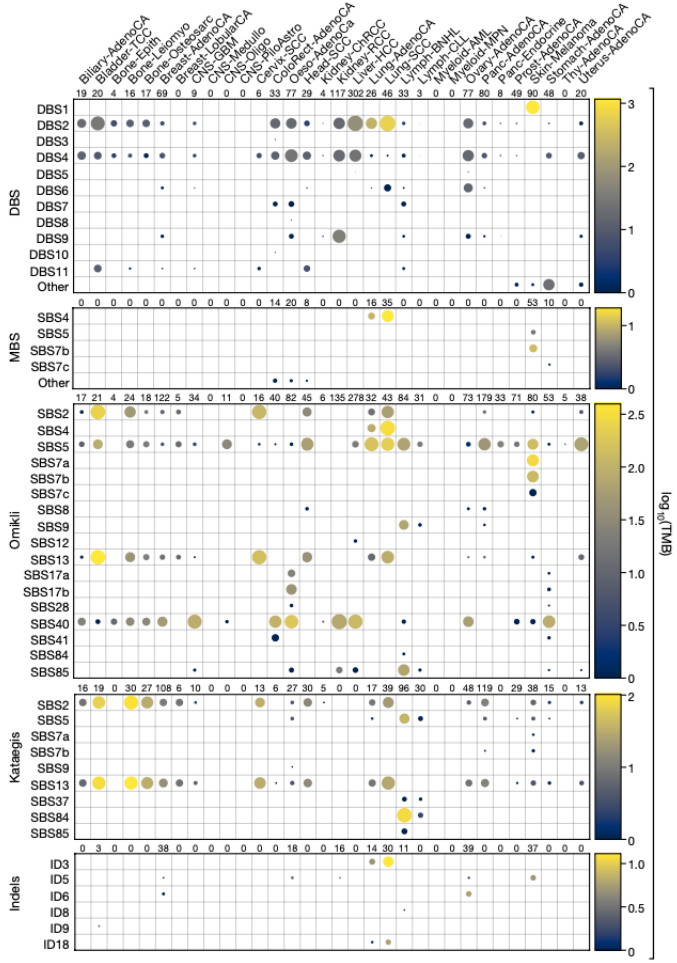


Fig. 2 | Mutational processes that underlie clustered events. Each circle represents the activity of a signature for a given cancer type. The radius of the circle determines the proportion of samples with greater than a given number of mutations specific to each subclass; the colour reflects the median number of mutations per cancer type. A minimum of two samples are required per cancer type for visualization (Methods).

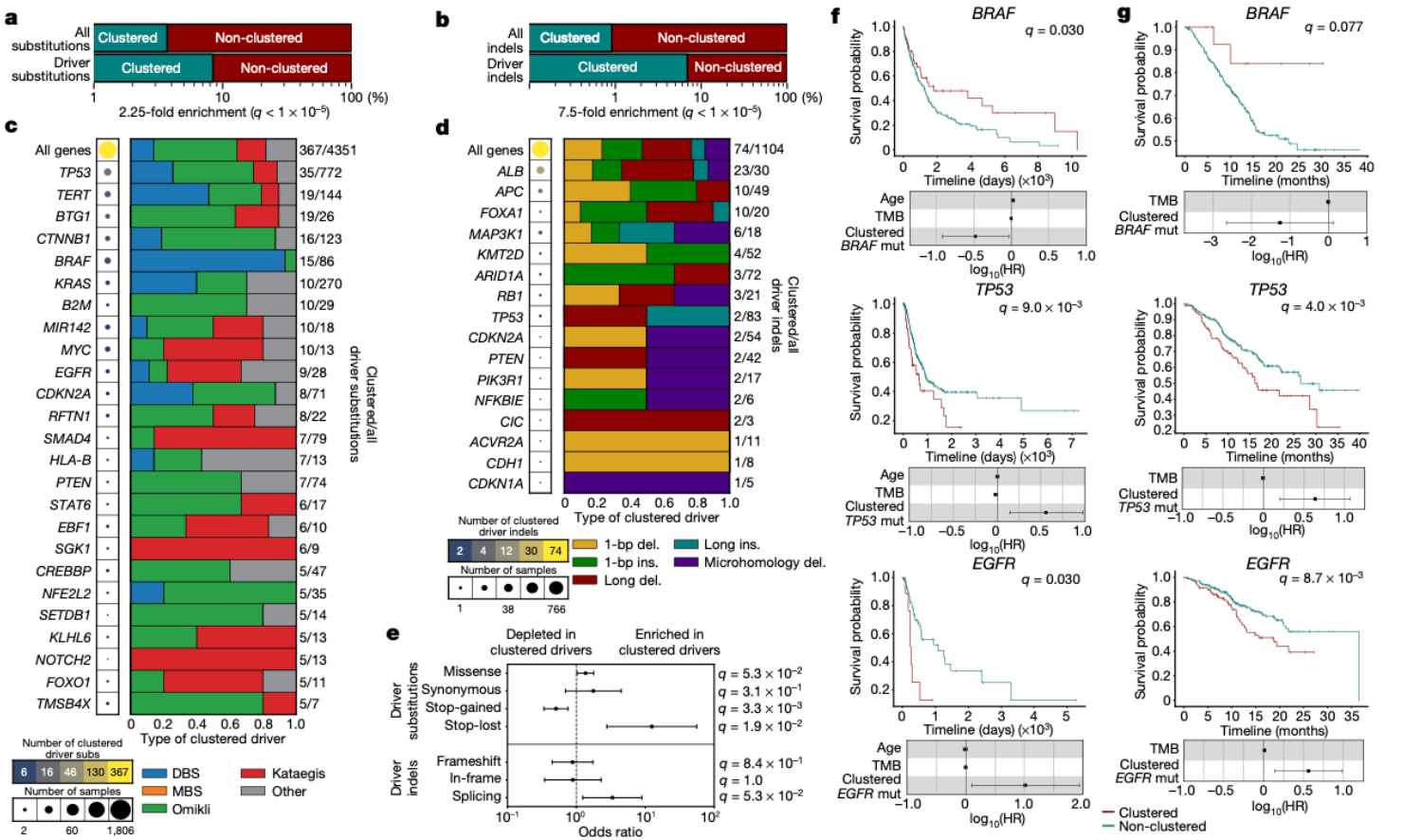


Fig. 3 | Panorama of clustered driver mutations in human cancer.

deleterious and $n = 50$ synonymous indels). All events were overlapped with the

Kobayashi et al. Silent mutations reveal therapeutic vulnerability in RAS Q61 cancers

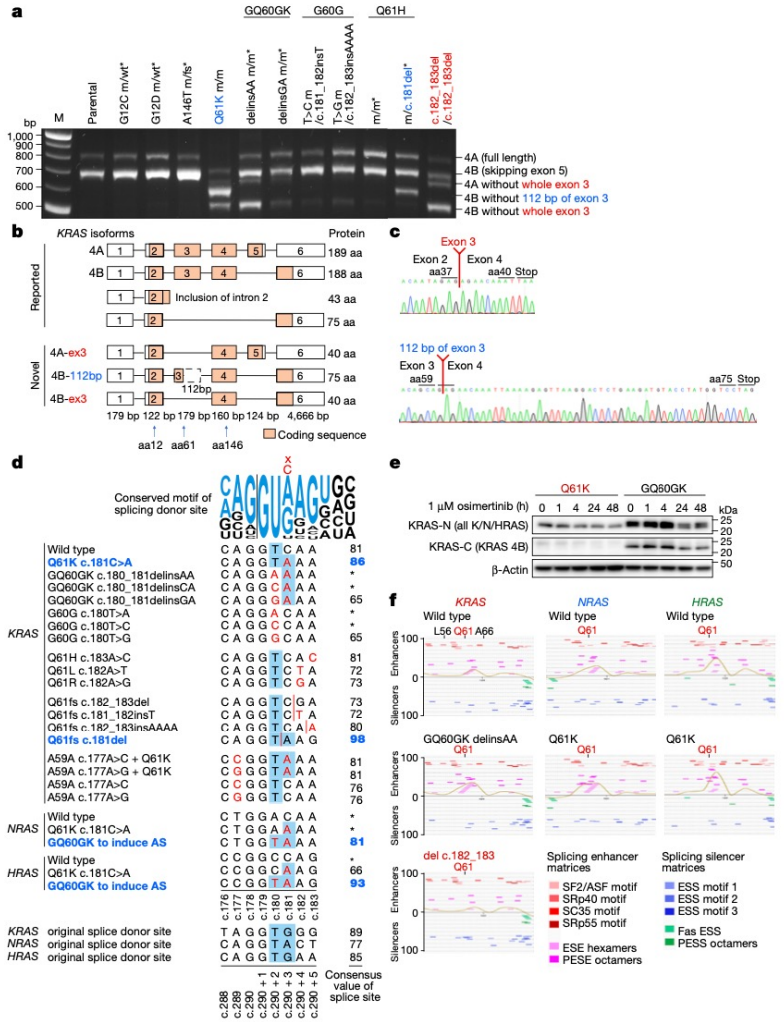


Fig. 3 | Silent mutation in *KRAS*^{G60G} is necessary for correct splicing of *KRAS*^{Q61K}. **a**, *KRAS*-specific PCR amplicons of cDNA, generated from

of splice site were estimated by Human Splicing Finder. *KRAS* mutants with cryptic splice donor sites and their consensus values are shown in blue.

Pataskar et al. Tryptophan depletion results in tryptophan-to-phenylalanine substitutants

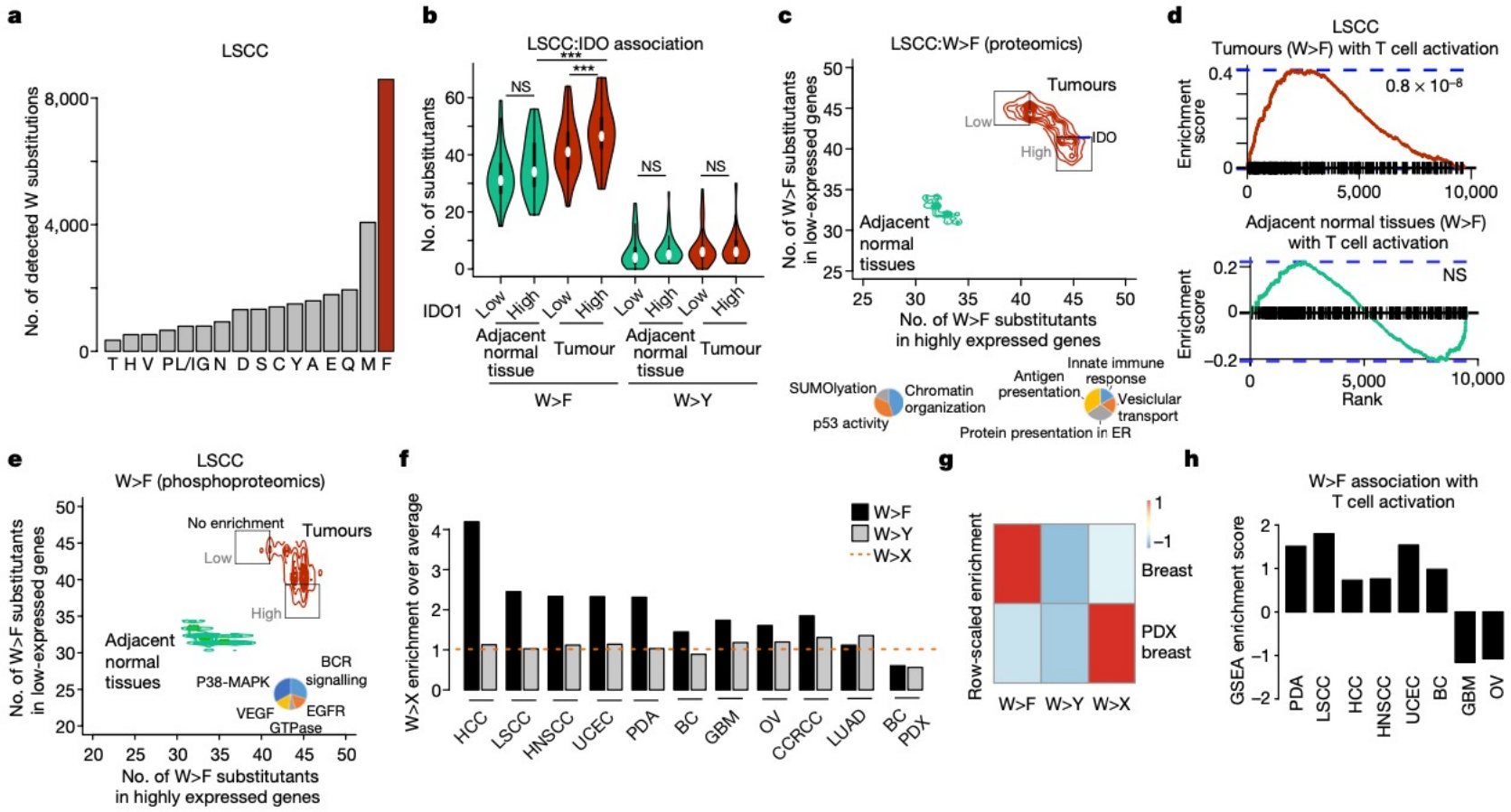
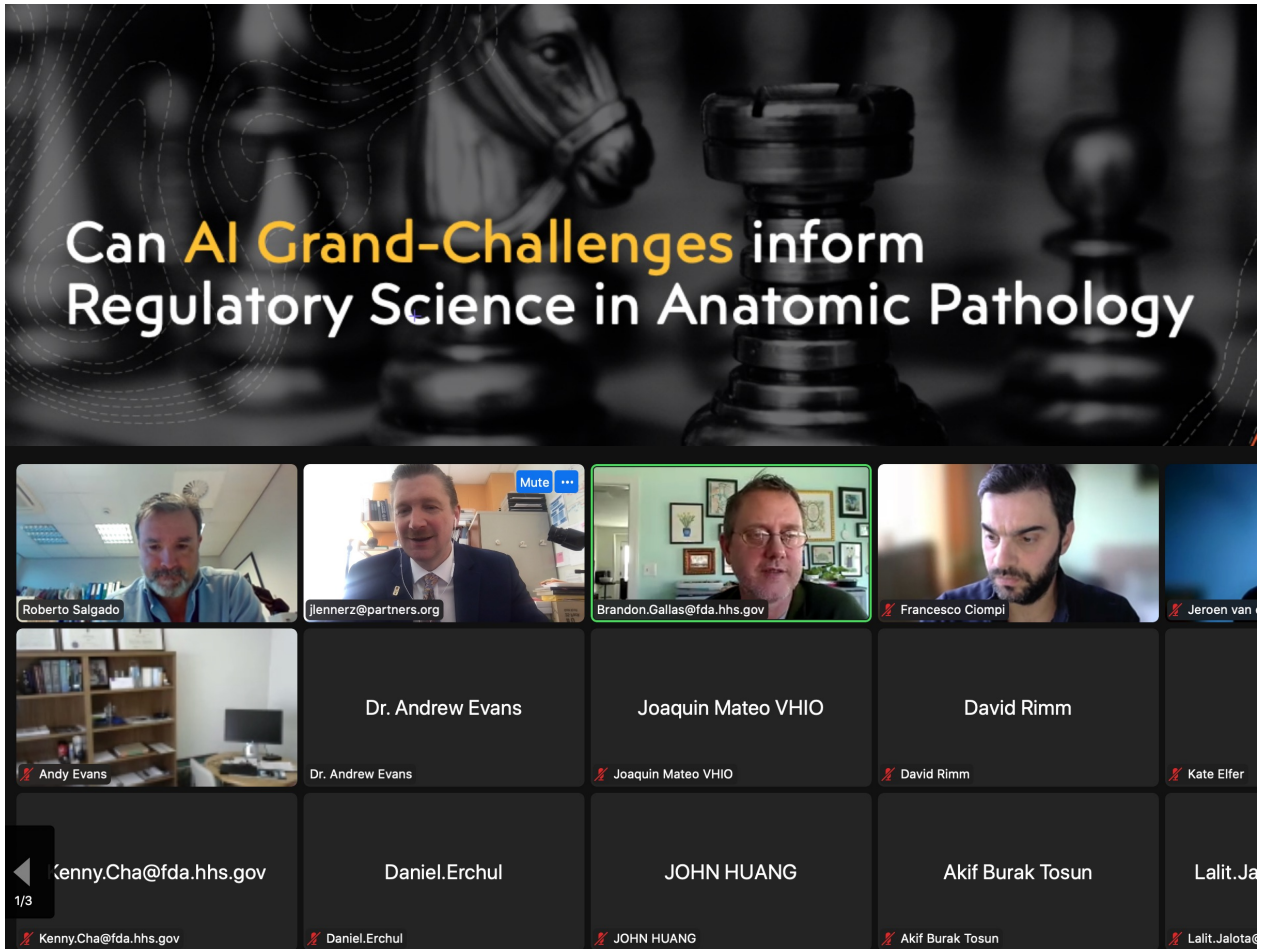


Fig. 3 | Detection of W>F substitutants in cancer proteomes. a, Bar plot

expressed at higher level when the number of W>F substitutants is higher in

News & Events

News & Events



- New date for live discussion is **Monday, April 25, 2022 at 12:00-1:00PM** Eastern time

News & Events

- API Summit in Pittsburgh on May 9-12, 2022
- PathML Presentation featuring Renato Umeton, PhD and Jacob Rosenthal, MSc (DFCI) – June 2022, time & date TBD
- Next Steering Committee Wednesday, April 27, 2022 at 3:00-4:00 PM Eastern Time