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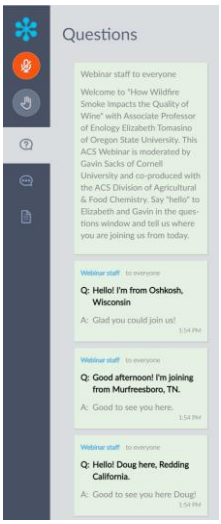

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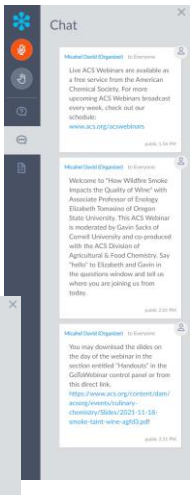

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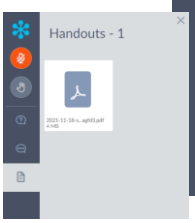

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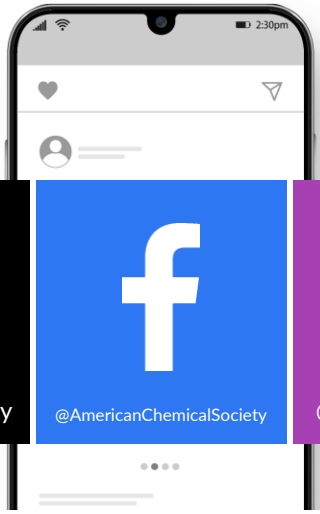

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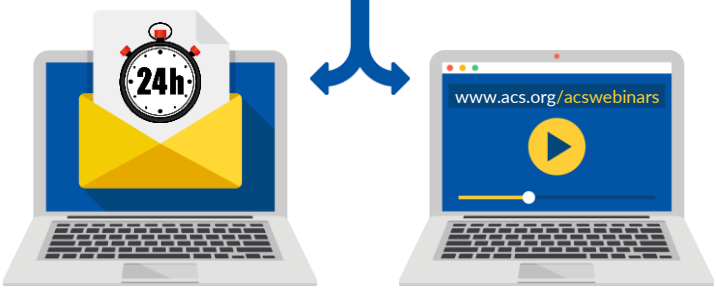

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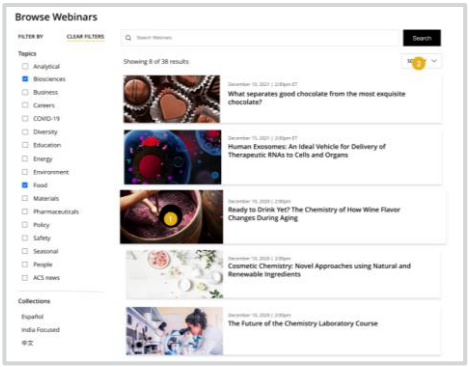

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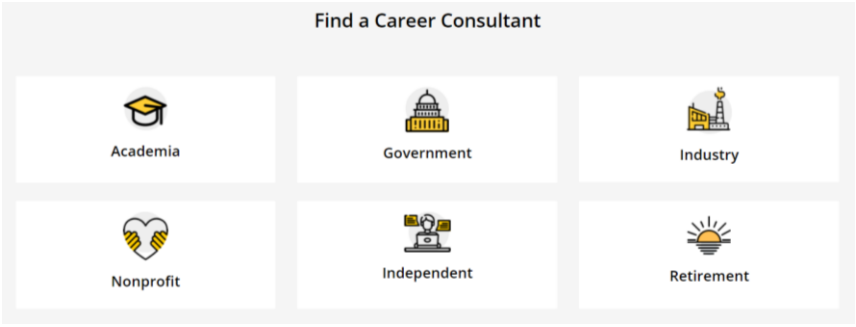

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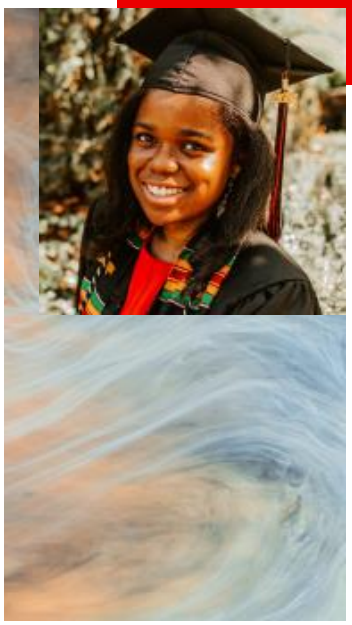

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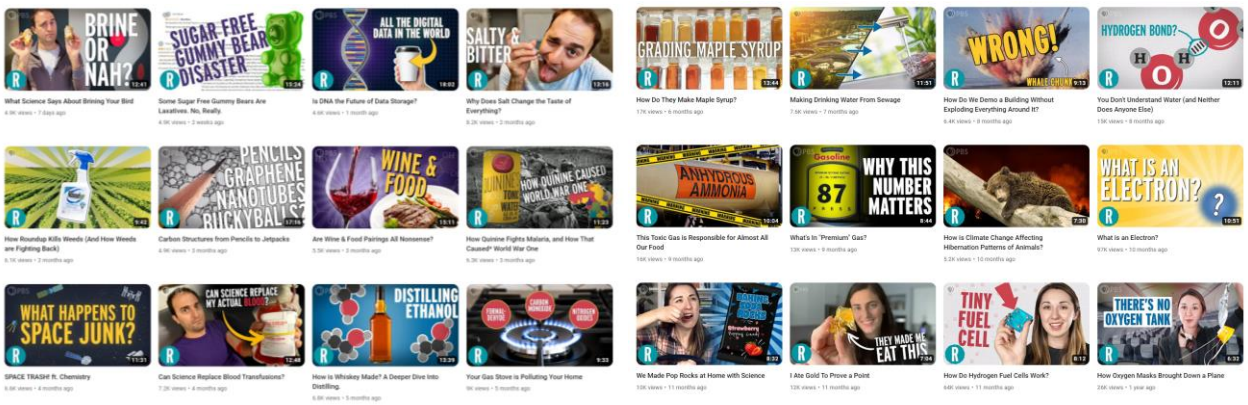

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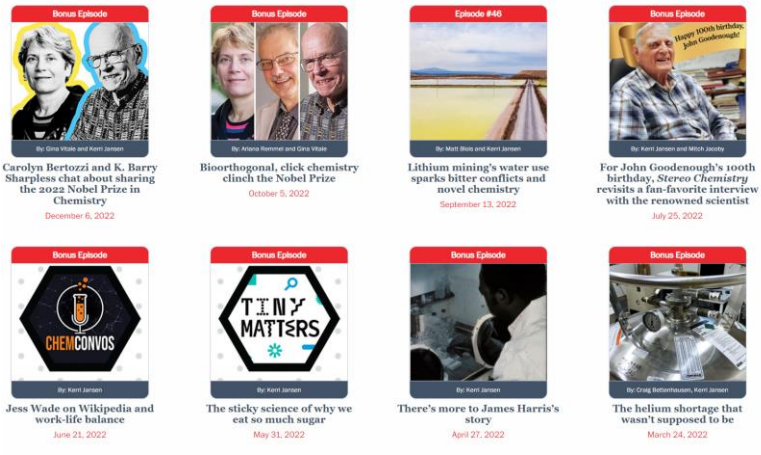

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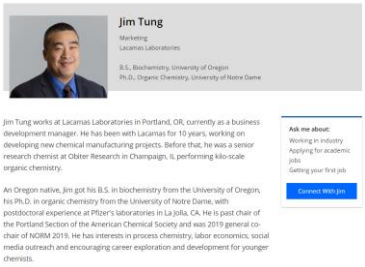

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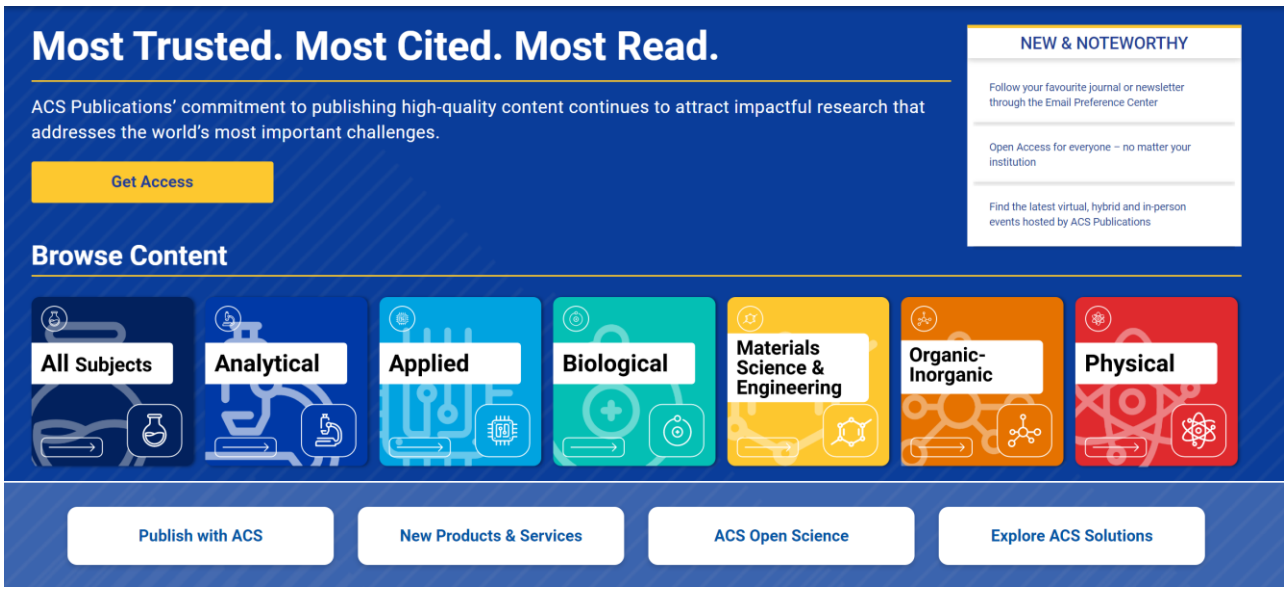

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ACS Webinars on Diversity
Covering diversity and inclusion at the workplace

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See what ACS Publications is doing for fostering inclusivity in scholarly publishing

ACS Volunteer and ACS Meetings Code of Conduct
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Quick Guide: How to host inclusive in-person events
Recommendations and best practices to ensure that your events can accommodate everyone.

Diversity, Equity, Inclusion, and Respect
**Adapted from definitions from the Ford Foundation Center for Social Justice:

Equity**
Seeks to ensure fair treatment, equality of opportunity, and fairness in access to information and resources for all. We believe this is only possible in an environment built on respect and dignity. Equity requires the identification and elimination of barriers that have prevented the full participation of some groups.

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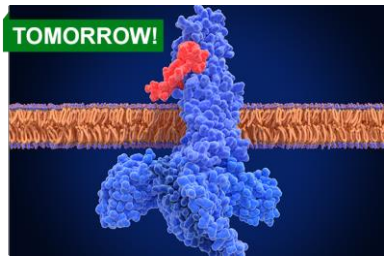

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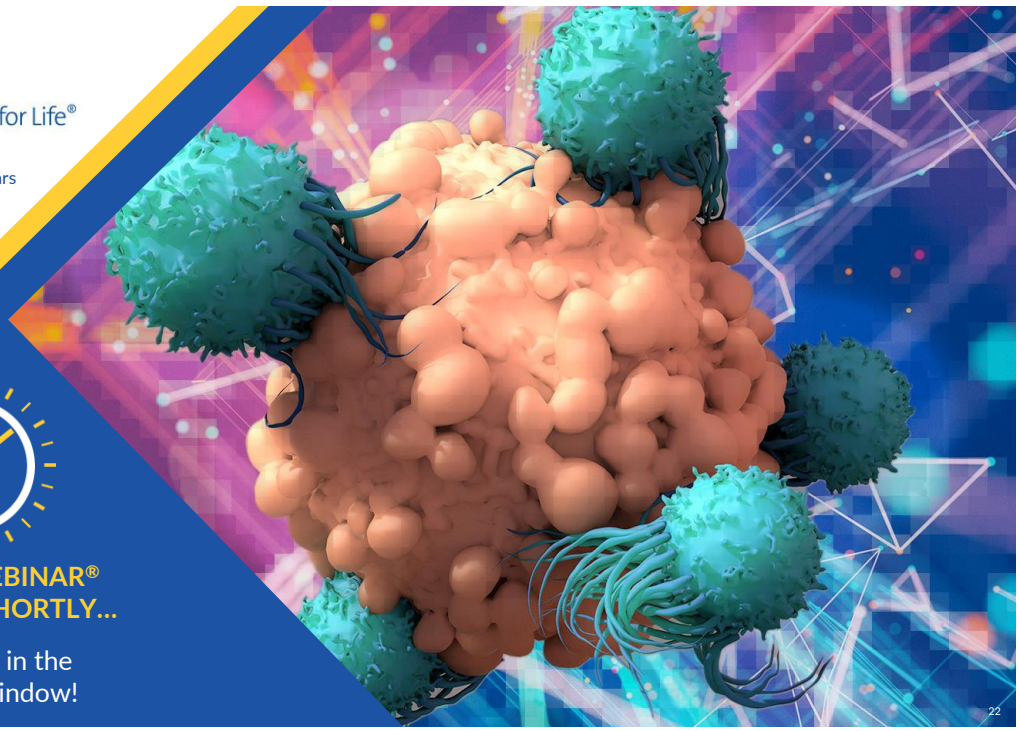

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Immuno-oncology: Big Data Insights in the Quest to Cure Cancer

KAVITA IYER, PhD
Scientific Content Creator, ACSI India

AIK CHOON TAN, PhD
Senior Director of Data Science, Huntsman Cancer Institute, University of Utah

HISHAM HAMADEH, PhD
Senior Vice President and Global Head of Data Science & AI, Genmab

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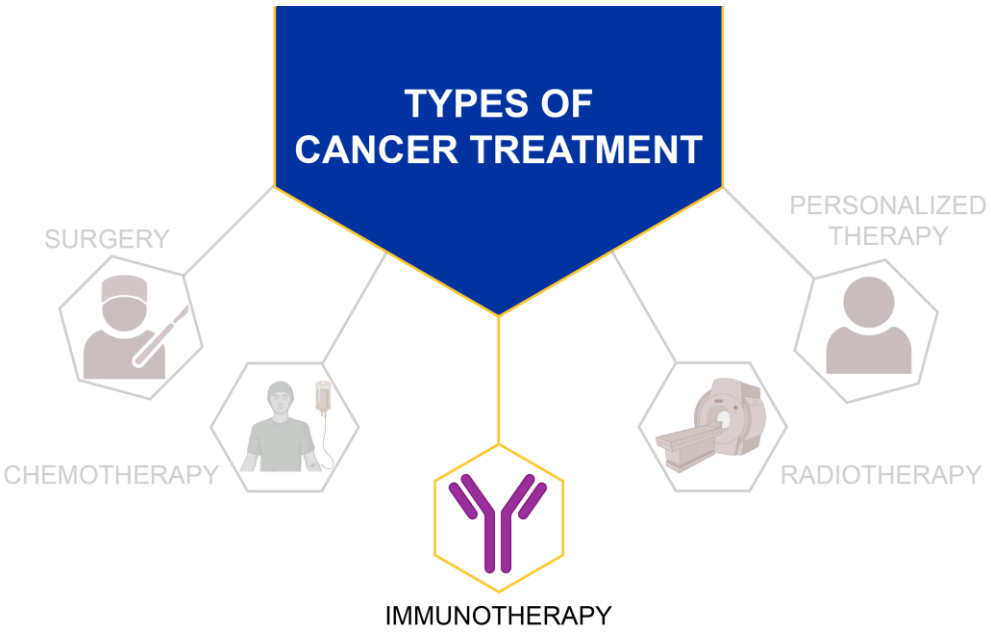

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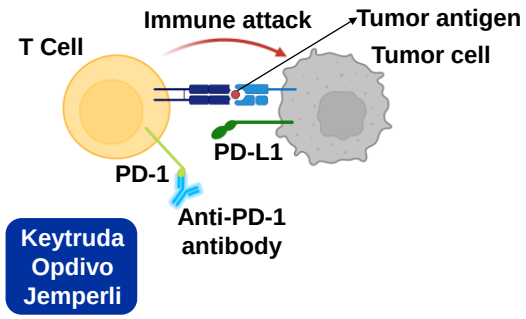
Immunotherapy

Harnesses the body's immune system to recognize, target, and eliminate tumor cells

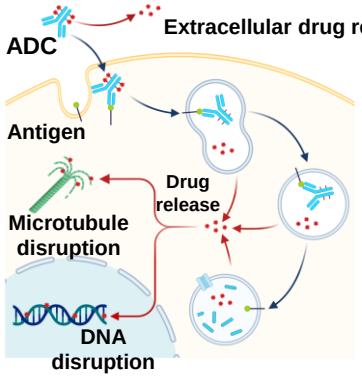
Immune checkpoint inhibitors (ICIs)



Keytruda
Opdivo
Jemperli

Adapted from "Immune Checkpoint Inhibitor Against Tumor Cell". https://app.biorender.com/illustrations/65ccfc9d027659083a30aea

Antibody-drug conjugates (ADCs)



Kadcyla
Besponsa
Elahere

Adapted from "Antibody-Drug Conjugate Drug Release". Retrieved from https://app.biorender.com/illustrations/65ccdf8bc25fde8f1f59b442

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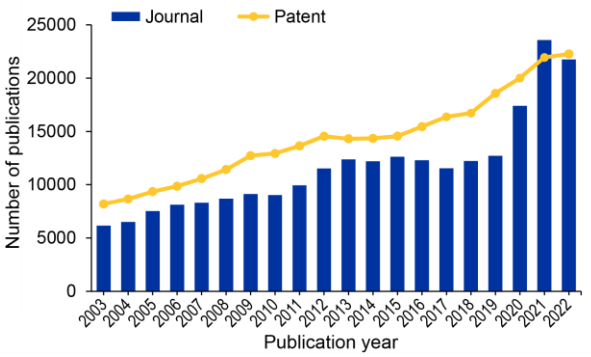
The rapidly evolving field of immuno-oncology

A promising treatment option

Overall publication trends



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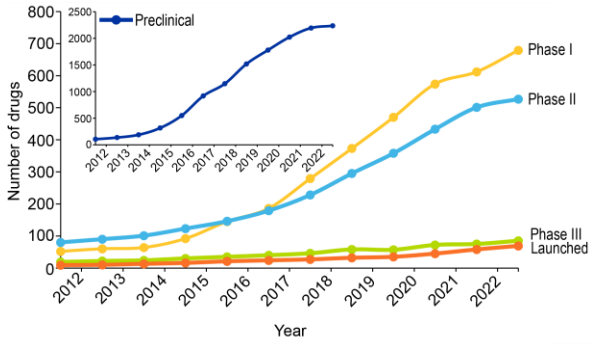
Clinical trials



Source: Pharmaprojects

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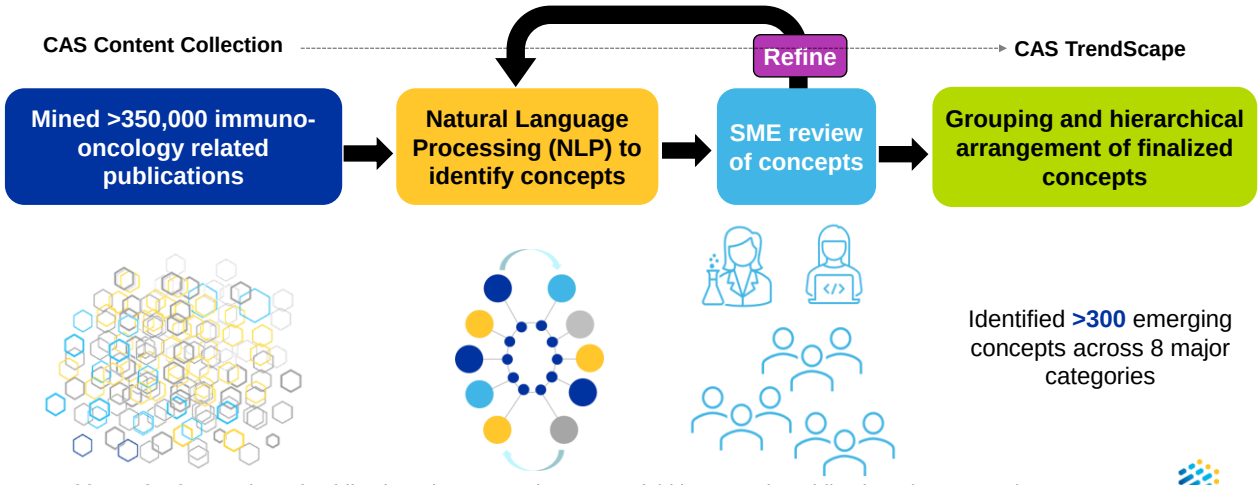
Identifying emerging concepts

Natural language processing (NLP)-driven analysis of large dataset combined



Identified **>300** emerging concepts across 8 major categories

Ranking criteria: number of publications (2020-2022); average fold increase in publications (2020-2022)

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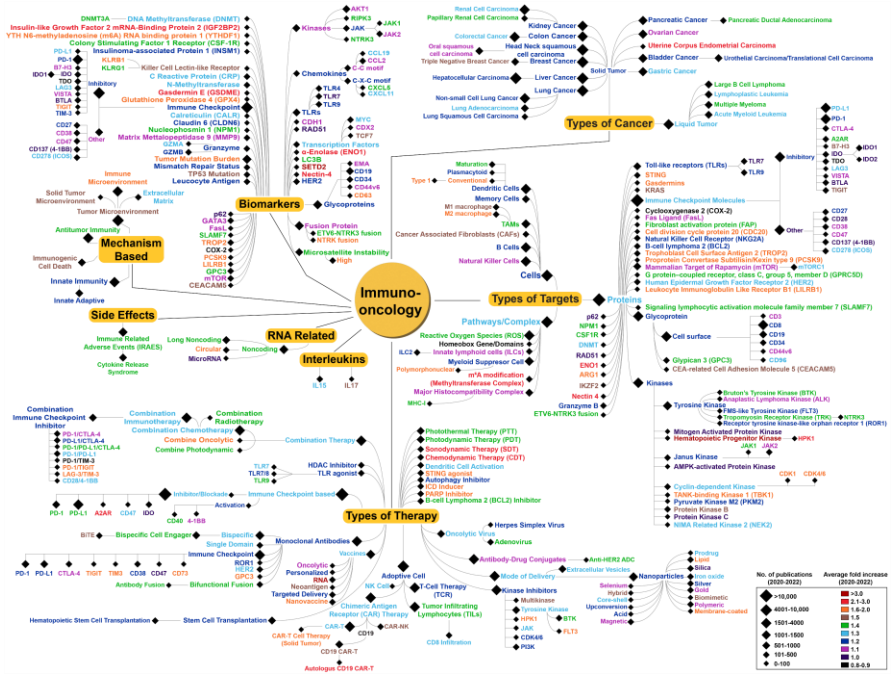

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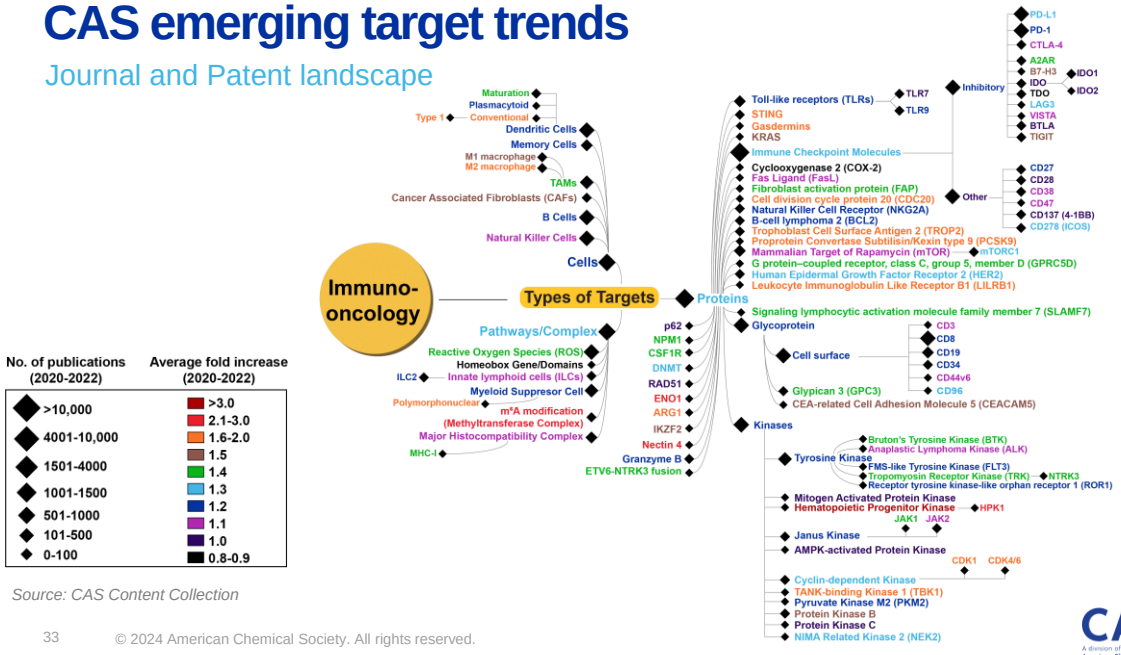
CAS emerging target trends

Journal and Patent landscape



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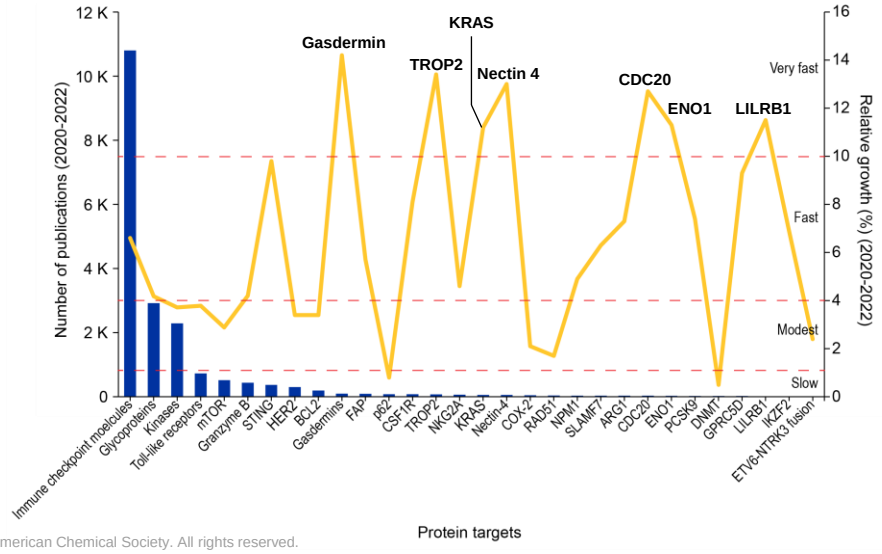
Target proteins

Fast growing while still in early phase



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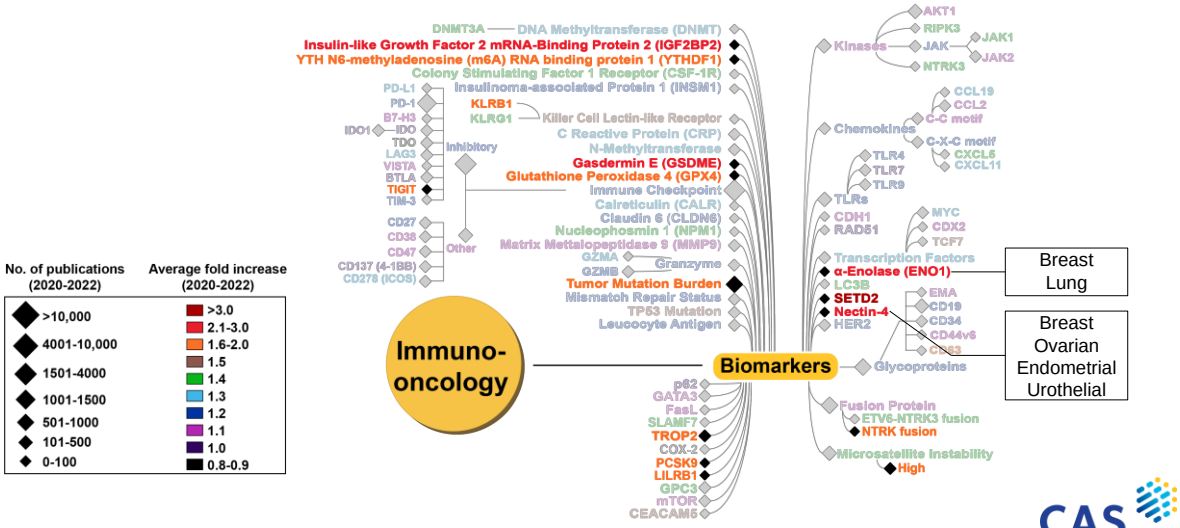
CAS emerging biomarker trends

Journal and Patent landscape



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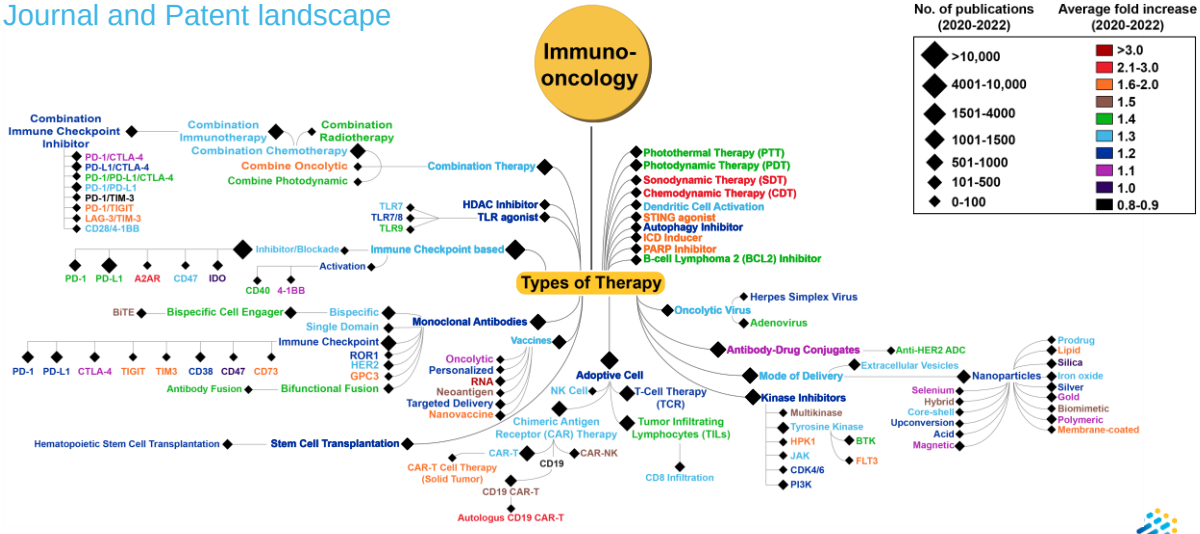
CAS emerging immunotherapy trends

Journal and Patent landscape



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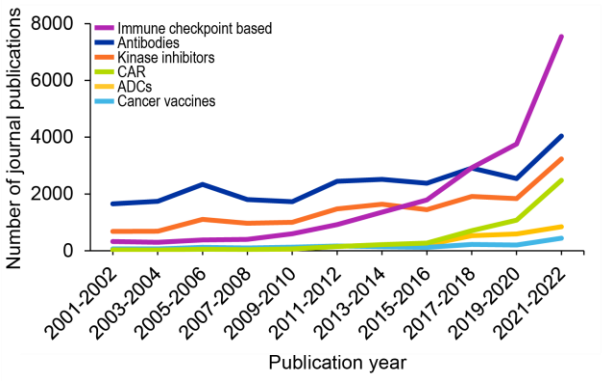
Emerging concepts in journal and patent publications

Publication trends of selected emerging types of immunotherapy

Journal



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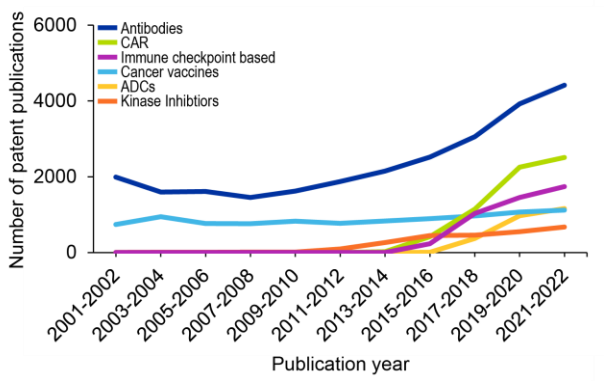
Patent



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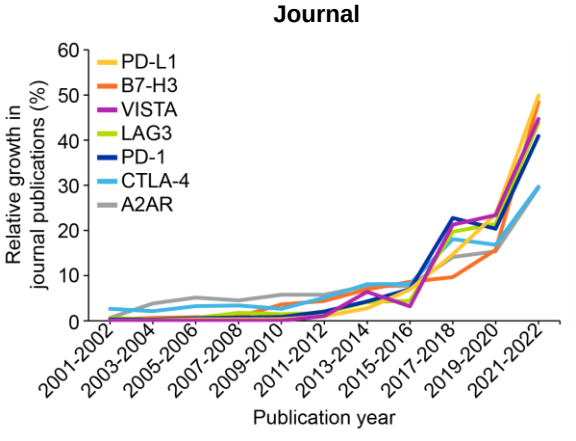
Emerging concepts in journal and patent publications

Publication trends of selected immune checkpoint inhibitors

Journal



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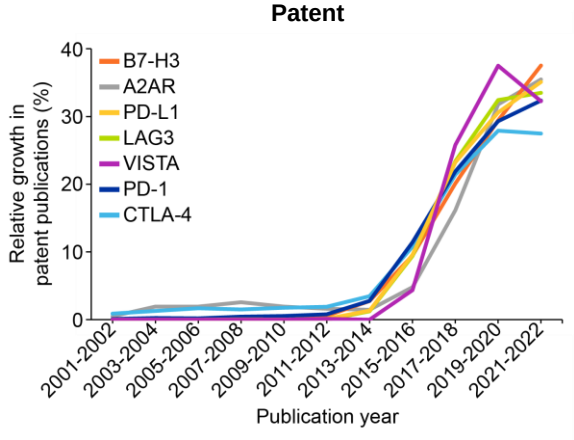

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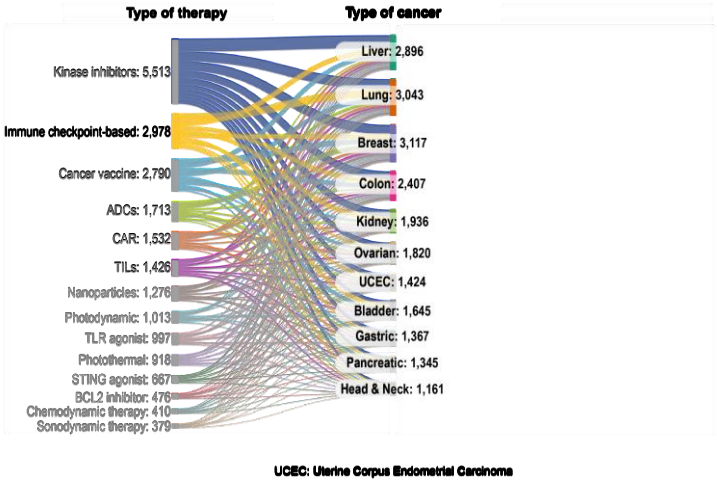
Co-occurring concepts in journal and patent publications

Co-occurrences between emerging cancer types (solid tumors) and therapies



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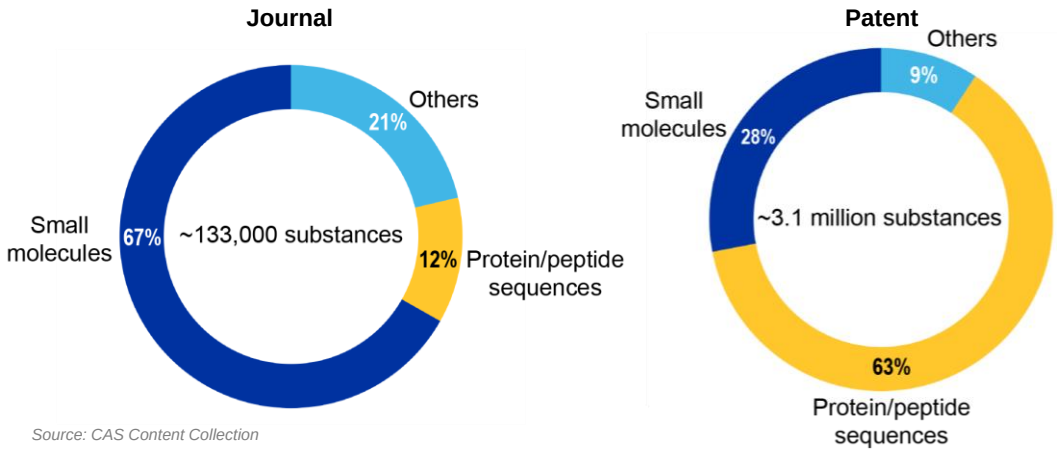
Substance data trends: Higher commercial interest in protein/peptide sequences

>3.2 million substances associated with immuno-oncology (2012-2022)



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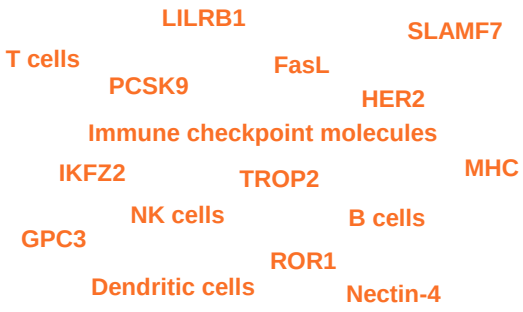
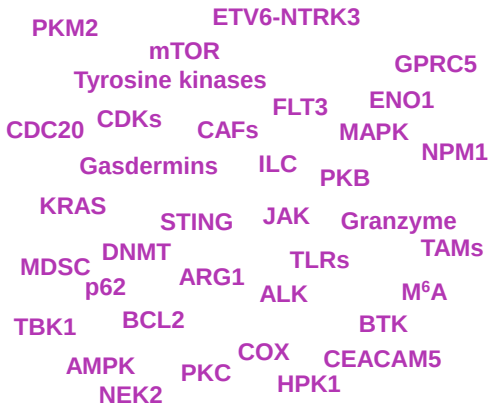
Substance data trends for patent publications

Biologics and small molecules associated with emerging therapeutic targets in patent publications

Higher number of associated biologics



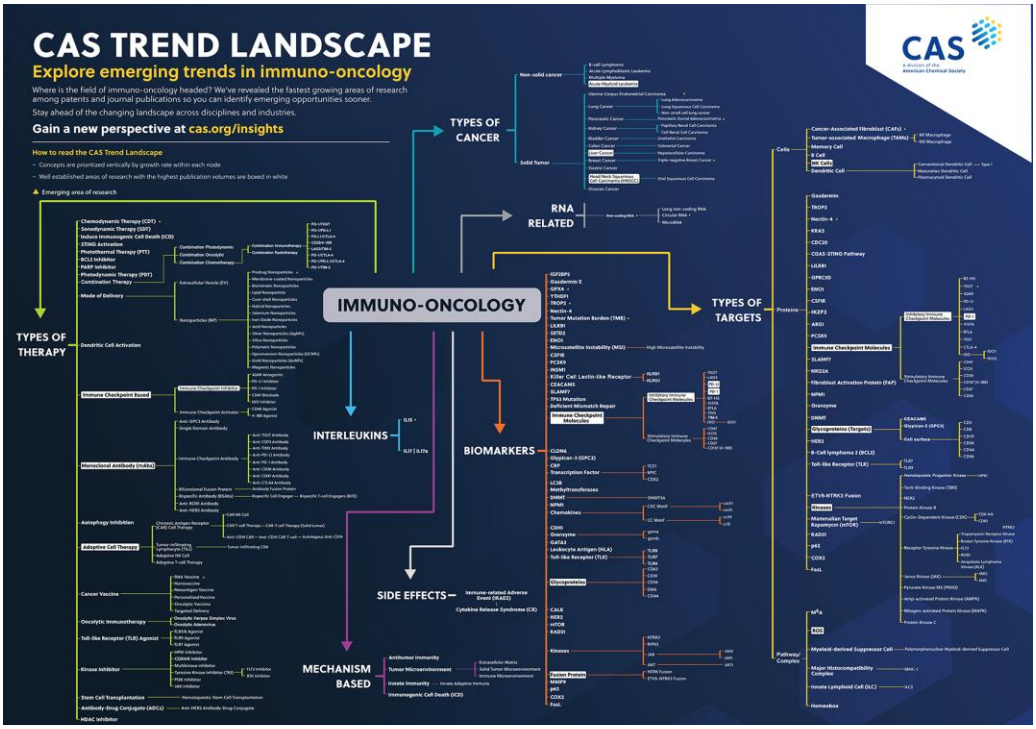
Higher number of associated small molecules



Source: CAS Content Collection

In Summary

- Sustained and increasing interest in immuno-oncology as seen by publication trends for journal articles, clinical trials, approved drugs and investments
- Identified >300 emerging concepts from ~350,000 immuno-oncology related publications from the CAS Content Collection using novel NLP-driven analysis
- “Trend Landscape” map – visual representation of emerging concepts along with associated metrics
- Increase in publications associated with immune checkpoint molecules such as TIGIT, B7-H3, A2AR, LAG3
- Targetable biomarkers that are emerging: ENO-1, nectin-4, TROP2, PCSK9, LILRB1 among others
- Biologics appear to be of greater commercial interest than small molecules



Acknowledgement

CAS colleagues and teammates

- Julian Ivanov
- Rumiana Tenchov
- Krittika Ralhan
- Yacid Rodriguez
- Janet Sasso
- Sabina Scott
- Qiongqiong Angela Zhou

Gain insights on immuno-oncology and more

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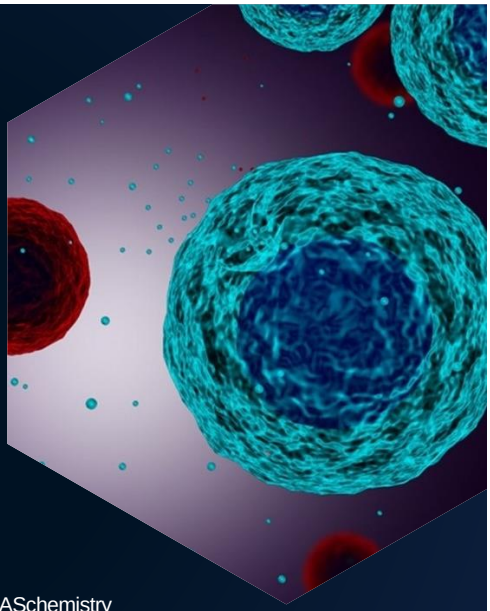

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Developing Biomarkers for Immuno-oncology from Big Data

Aik Choon Tan, Ph.D.
Senior Director of Data Science, Huntsman Cancer Institute
And Jon M. and Karen Huntsman Endowed Chair in Cancer Data Science and Professor, Departments of Oncological Sciences and Biomedical Informatics, University of Utah

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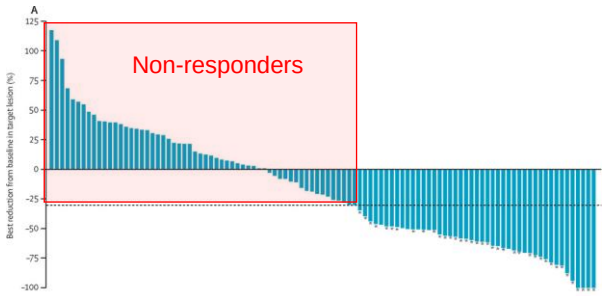
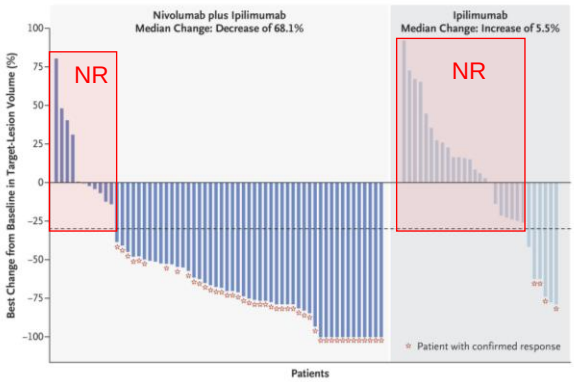
Predictive Biomarkers for ICIs

Nivolumab
(Weber et al ***Lancet Onc*** 2015)

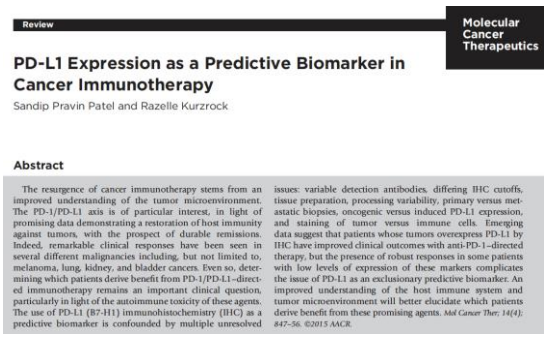
Nivolumab



Nivolumab + Ipilimumab
(Postow et al ***NEJM*** 2015)



PD-L1 expression as Biomarker



Review

Molecular Cancer Therapeutics

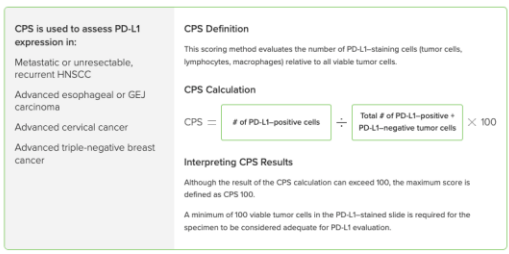
PD-L1 Expression as a Predictive Biomarker in Cancer Immunotherapy

Sandip Pravin Patel and Razelle Kurzrock

Abstract

The resurgence of cancer immunotherapy stems from an improved understanding of the tumor microenvironment. The PD-1/PD-L1 axis is of particular interest, in light of promising data demonstrating a restoration of host immunity against tumors, with the prospect of durable remissions. Indeed, remarkable clinical responses have been seen in several different malignancies including, but not limited to, melanoma, lung, kidney, and bladder cancers. Even so, determining which patients derive benefit from PD-1/PD-L1–directed immunotherapy remains an important clinical question, particularly in light of the autoimmune toxicity of these agents. The use of PD-L1 (B7-H1) immunohistochemistry (IHC) as a predictive biomarker is confounded by multiple unresolved issues: variable detection antibodies, differing IHC cutoffs, tissue preparation, processing variability, primary versus metastatic biopsies, oncogenic versus induced PD-L1 expression, and staining of tumor versus immune cells. Emerging data suggest that patients whose tumors overexpress PD-L1 by IHC have improved clinical outcomes with anti-PD-1–directed therapy, but the presence of robust responses in some patients with low levels of expression of these markers complicates the issue of PD-L1 as an exclusionary predictive biomarker. An improved understanding of the host immune system and tumor microenvironment will better elucidate which patients derive benefit from these promising agents. *Mol Cancer Ther; 14(4): 847–56. ©2015 AACR.*

CPS (Combined Positive Score)[1]



CPS is used to assess PD-L1 expression in:

Metastatic or unresectable, recurrent HNSCC

Advanced esophageal or GEJ carcinoma

Advanced cervical cancer

Advanced triple-negative breast cancer

CPS Definition

This scoring method evaluates the number of PD-L1–staining cells (tumor cells, lymphocytes, macrophages) relative to all viable tumor cells.

CPS Calculation

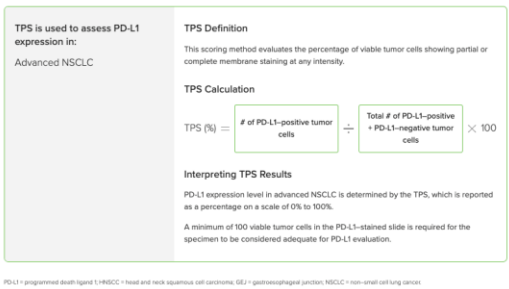
CPS = (# of PD-L1–positive cells) ÷ (Total # of PD-L1–positive + PD-L1–negative tumor cells) × 100

Interpreting CPS Results

Although the result of the CPS calculation can exceed 100, the maximum score is defined as CPS 100.

A minimum of 100 viable tumor cells in the PD-L1–stained slide is required for the specimen to be considered adequate for PD-L1 evaluation.

TPS (Tumor Proportion Score)[1]



TPS is used to assess PD-L1 expression in:

Advanced NSCLC

TPS Definition

This scoring method evaluates the percentage of viable tumor cells showing partial or complete membrane staining at any intensity.

TPS Calculation

TPS (%) = (# of PD-L1–positive tumor cells) ÷ (Total # of PD-L1–positive + PD-L1–negative tumor cells) × 100

Interpreting TPS Results

PD-L1 expression level in advanced NSCLC is determined by the TPS, which is reported as a percentage on a scale of 0% to 100%.

A minimum of 100 viable tumor cells in the PD-L1–stained slide is required for the specimen to be considered adequate for PD-L1 evaluation.

PD-L1 = programmed death ligand 1; HNSCC = head and neck squamous cell carcinoma; GEJ = gastroesophageal junction; NSCLC = non–small cell lung cancer.

Cut-off thresholds:
CPS ⩾ 1 or TPS ⩾ 1

Genomics-based Biomarkers

Fancello et al. Journal for ImmunoTherapy of Cancer (2019) 7:183
https://doi.org/10.1186/s40425-019-0647-4

Journal for ImmunoTherapy of Cancer

Tumor Mutation Burden (TMB)

REVIEW Open Access

Tumor mutational burden quantification from targeted gene panels: major advancements and challenges

Laura Fancello[1*], Sara Gandini[1], Pier Giuseppe Pelicci[1,2] and Luca Mazzarella[1,3*]

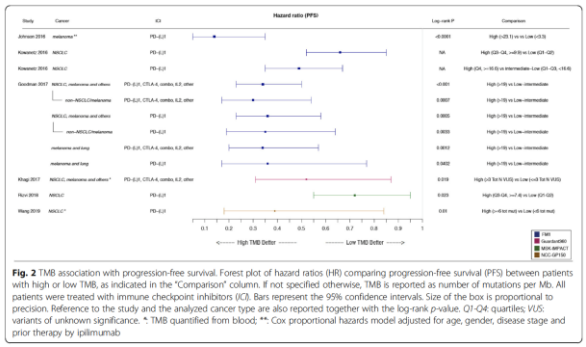


Fig. 2 TMB association with progression-free survival. Forest plot of hazard ratios (HR) comparing progression-free survival (PFS) between patients with high or low TMB, as indicated in the "Comparison" column. If not specified otherwise, TMB is reported as number of mutations per Mb. All patients were treated with immune checkpoint inhibitors (ICI). Bars represent the 95% confidence intervals. Size of the box is proportional to precision. Reference to the study and the analyzed cancer type are also reported together with the log-rank *p*-value. *Q1-Q4*: quartiles; *VUS*: variants of unknown significance. *: TMB quantified from blood; **: Cox proportional hazards model adjusted for age, gender, disease stage and prior therapy by ipilimumab

MSI-H or dMMR

The NEW ENGLAND JOURNAL of MEDICINE
DECEMBER 3, 2020

Pembrolizumab in Microsatellite-Instability–High Advanced Colorectal Cancer

T. André, K.-K. Shiu, T.W. Kim, B.V. Jensen, L.H. Jensen, C. Punt, D. Smith, R. García-Carbonero, M. Benavides, P. Gibbs, C. de la Fouchardiere, F. Rivera, E. Elez, J. Bendell, D.T. Le, T. Yoshino, E. Van Cutsem, P. Yang, M.Z.H. Farooqui, P. Marinello, and L.A. Diaz, Jr., for the KEYNOTE-177 Investigators*

ABSTRACT

BACKGROUND
Programmed death 1 (PD-1) blockade has clinical benefit in microsatellite-instability–high (MSI-H) or mismatch-repair–deficient (dMMR) tumors after previous therapy. The efficacy of PD-1 blockade as compared with chemotherapy as first-line therapy for MSI-H–dMMR, advanced or metastatic colorectal cancer is unknown.

METHODS
In this phase 3, open-label trial, 307 patients with metastatic MSI-H–dMMR colorectal cancer who had not previously received treatment were randomly assigned, in a 1:1 ratio, to receive pembrolizumab at a dose of 200 mg every 3 weeks or chemotherapy (5-fluorouracil–based therapy with or without bevacizumab or cetuximab) every 2 weeks. Patients receiving chemotherapy could cross over to pembrolizumab therapy after disease progression. The two primary end points were progression-free survival and overall survival.

RESULTS
At the second interim analysis, after a median follow-up (from randomization to data cutoff) of 32.4 months (range, 24.0 to 48.3), pembrolizumab was superior to chemotherapy with respect to progression-free survival (median, 16.5 vs. 8.2 months; hazard ratio, 0.60; 95% confidence interval [CI], 0.45 to 0.80; P=0.0002). The estimated restricted mean survival after 24 months of follow-up was 13.7 months (range, 12.0 to 15.4) as compared with 10.0 months (range, 9.4 to 12.2). As of the data cutoff date, 56 patients in the pembrolizumab group and 69 in the chemotherapy group had died. Data on overall survival were still evolving (66% of required events had occurred) and remain blinded until the final analysis. An overall response (complete or partial response), as evaluated with Response Evaluation Criteria in Solid Tumors (RECIST), version 1.1, was observed in 43.8% of the patients in the pembrolizumab group and 33.1% in the chemotherapy group. Among patients with an overall response, 87% in the pembrolizumab group, as compared with 35% of patients in the chemotherapy group, had ongoing responses at 24 months. Treatment-related adverse events of grade 3 or higher occurred in 22% of the patients in the pembrolizumab group, as compared with 66% (including one patient who died) in the chemotherapy group.

CONCLUSIONS
Pembrolizumab led to significantly longer progression-free survival than chemotherapy when received as first-line therapy for MSI-H–dMMR, metastatic colorectal cancer, with fewer treatment-related adverse events. (Funded by Merck Sharp and Dohme and by Stand Up to Cancer; KEYNOTE-177 ClinicalTrials.gov number, NCT02563002.)

The New England Journal of Medicine
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Transcriptomics-based Biomarkers

RESEARCH ARTICLE The Journal of Clinical Investigation

IFN-γ–related mRNA profile predicts clinical response to PD-1 blockade

Mark Ayers,[1] Jared Lunceford,[1] Michael Nebozhyn,[1] Erin Murphy,[1] Andrey Loboda,[1] David R. Kaufman,[1] Andrew Albright,[1] Jonathan D. Cheng,[2] S. Peter Kang,[3] Veena Shankaran,[4] Sarina A. Piha-Paul,[5] Jennifer Yearley,[1] Tanguy Y. Seiwert,[6] Antoni Ribas,[7] and Terrill K. McClanahan[1]

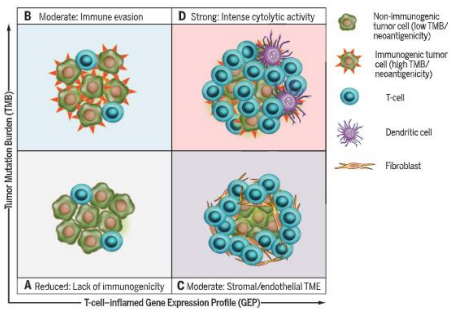
Programmed death-1–directed (PD-1–directed) immune checkpoint blockade results in durable antitumor activity in many advanced malignancies. Recent studies suggest that IFN-γ is a critical driver of programmed death ligand-1 (PD-L1) expression in cancer and host cells, and baseline intratumoral T cell infiltration may improve response likelihood to anti–PD-1 therapies, including pembrolizumab. However, whether quantifying T cell–inflamed microenvironment is a useful pan-tumor determinant of PD-1–directed therapy response has not been rigorously evaluated. Here, we analyzed gene expression profiles (GEPs) using RNA from baseline tumor samples of pembrolizumab-treated patients. We identified immune-related signatures correlating with clinical benefit using a learn-and-confirm paradigm based on data from different clinical studies of pembrolizumab, starting with a small pilot of 15 melanoma patients and eventually defining a pan-tumor T cell–inflamed GEP in 220 patients with 6 cancers. Predictive value was independently confirmed and compared with that of PD-L1 immunohistochemistry in 96 patients with head and neck squamous cell carcinoma. The T cell–inflamed GEP contained IFN-γ–responsive genes related to antigen presentation, chemokine expression, cytotoxic activity, and adaptive immune resistance, and these features were necessary, but not always sufficient, for clinical benefit. The T cell–inflamed GEP has been developed into a clinical-grade assay that is currently being evaluated in ongoing pembrolizumab trials.

RESEARCH ARTICLE
CANCER BIOMARKERS

Pan-tumor genomic biomarkers for PD-1 checkpoint blockade–based immunotherapy

Razvan Cristescu[1*], Robin Mogg[1†], Mark Ayers[1], Andrew Albright[1], Erin Murphy[1], Jennifer Yearley[1], Xiawei Sher[1], Xiao Qiao Liu[1], Hongzhao Lu[1], Michael Nebozhyn[1], Chunsheng Zhang[1], Jared K. Lunceford[1], Andrew Joe[1], Jonathan Cheng[2], Andrea L. Webber[2], Nagnatte Ibrahim[2], Elisabeth R. Plimack[3], Patrick A. Ott[3], Tanguy Y. Seiwert[4], Antoni Ribas[5], Terrill K. McClanahan[1], Joanne E. Tomassini[1], Andrey Loboda[1], David Kaufman[1†]

Programmed cell death protein–1 (PD-1) and programmed cell death ligand–1 (PD-L1) checkpoint blockade immunotherapy elicits durable antitumor effects in multiple cancers, but not all patients respond. We report the evaluation of >300 patient samples across 22 tumor types from four KEYNOTE clinical trials. Tumor mutational burden (TMB) and a T cell–inflamed gene expression profile (GEP) exhibited joint predictive utility in identifying responders and nonresponders to the PD-1 antibody pembrolizumab. TMB and GEP were independent predictive of response and demonstrated low correlation, suggesting that they capture distinct features of neoantigenicity and T cell activation. Analysis of The Cancer Genome Atlas data showed TMB and GEP to have a low correlation, and analysis by joint stratification revealed biomarker-defined patterns of targetable-resistance biology. These biomarkers may have utility in clinical trial design by guiding rational selection of anti–PD-1 monotherapy and combination immunotherapy regimens.



CLINICAL CANCER RESEARCH | TRANSLATIONAL CANCER MECHANISMS AND THERAPY

Transcriptomic Determinants of Response to Pembrolizumab Monotherapy across Solid Tumor Types

Razvan Cristescu[1], Michael Nebozhyn[1], Chunsheng Zhang[1], Andrew Albright[1], Julie Kobie[1], Lingkang Huang[1], Qing Zhao[1], Anran Wang[1], Hua Ma[1], Z. Alexander Cao[1], Michael Morrissey[1], Antoni Ribas[2], Petros Grivas[3], David W. Cescon[4], Terrill K. McClanahan[1], Alexandra Snyder[1], Mark Ayers[1], Jared Lunceford[1], and Andrey Loboda[1]

ABSTRACT

Purpose: To explore relationships between biological gene expression signatures and pembrolizumab response.

Experimental Design: RNA-sequencing data on baseline tumor tissue from 1,188 patients across seven tumor types treated with pembrolizumab monotherapy in nine clinical trials were used. A total of 11 prespecified gene expression signatures [18-gene T-cell–inflamed gene expression profile ($Tcell_{inf}GEP$), angiogenesis, hypoxia, glycolysis, proliferation, MYC, RAS, granulocytic myeloid-derived suppressor cell (gMDSC), monocytic myeloid-derived suppressor cell (mMDSC), stroma/epithelial-to-mesenchymal transition (EMT)/TGFβ, and WNT] were evaluated for their relationship to objective response rate (per RECIST, version 1.1). Logistic regression analysis of response for consensus signatures was adjusted for tumor type, Eastern Cooperative Oncology Group performance status, and $Tcell_{inf}GEP$, an approach equivalent to evaluating the association between response and the residuals of consensus signatures after detrending them for their relationship with the $Tcell_{inf}GEP$ (previously identified as a determinant of pembrolizumab response) and tumor type. Testing of the 10 prespecified non-$Tcell_{inf}GEP$ consensus signatures for negative association [except proliferation (hypothesized positive association)] with response was adjusted for multiplicity.

Results: Covariance patterns of the 11 signatures (including $Tcell_{inf}GEP$) identified in Merck–Moffitt and The Cancer Genome Atlas datasets showed highly concordant coexpression patterns in the RNA-sequencing data from pembrolizumab trials. $Tcell_{inf}GEP$ was positively associated with response; signatures for angiogenesis, mMDSC, and stroma/EMT/TGFβ were negatively associated with response to pembrolizumab monotherapy.

Conclusions: These findings suggest that features beyond IFNγ-related T-cell inflammation may be relevant to anti–programmed death 1 monotherapy response and may define other axes of tumor biology as candidates for pembrolizumab combinations.

See related commentary by Cho et al., p. 1479

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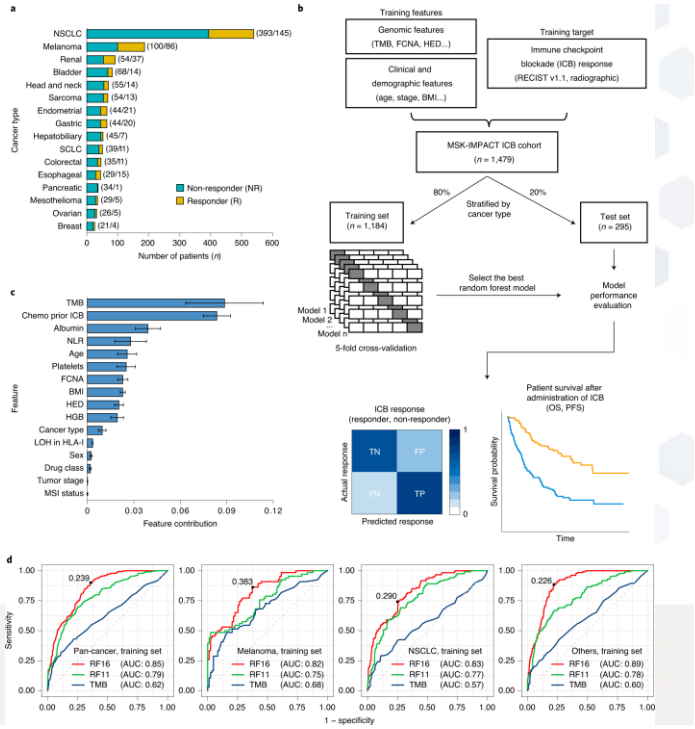
Genomics + Clinical Biomarkers

nature biotechnology
ARTICLES
https://doi.org/10.1038/s41587-021-01070-8

Improved prediction of immune checkpoint blockade efficacy across multiple cancer types

Diego Chowell[1,2,3,15,16], Seong-Keun Yoo[1,2,3,16], Cristina Valero[1,2,4,16], Alessandro Pastore[1,16], Chirag Krishna[5], Mark Lee[1,2], Douglas Hoen[1,2,3], Hongyu Shi[6,7], Daniel W. Kelly[8], Neal Patel[1,2,4], Vladimir Makarov[1,2,3], Xiaoxiao Ma[1,2,3], Lynda Vuong[1], Erich Y. Sabio[1], Kate Weiss[1,2], Fengshen Kuo[1,2], Tobias L. Lenz[9], Robert M. Samstein[10], Nadeem Riaz[1,2,11], Prasad S. Adusumilli[4], Vinod P. Balachandran[1,4], George Plitas[4], A. Ari Hakimi[1,2,4], Omar Abdel-Wahab[1], Alexander N. Shoushtari[12], Michael A. Postow[12], Robert J. Motzer[12], Marc Ladanyi[13], Ahmet Zehir[13], Michael F. Berger[13], Mithat Gönen[7], Luc G. T. Morris[1,2,4] ✉, Nils Weinhold[2,11] ✉ and Timothy A. Chan[1,2,3,11,14] ✉

Only a fraction of patients with cancer respond to immune checkpoint blockade (ICB) treatment, but current decision-making procedures have limited accuracy. In this study, we developed a machine learning model to predict ICB response by integrating genomic, molecular, demographic and clinical data from a comprehensively curated cohort (MSK-IMPACT) with 1,479 patients treated with ICB across 16 different cancer types. In a retrospective analysis, the model achieved high sensitivity and specificity in predicting clinical response to immunotherapy and predicted both overall survival and progression-free survival in the test data across different cancer types. Our model significantly outperformed predictions based on tumor mutational burden, which was recently approved by the U.S. Food and Drug Administration for this purpose[1]. Additionally, the model provides quantitative assessments of the model features that are most salient for the predictions. We anticipate that this approach will substantially improve clinical decision-making in immunotherapy and inform future interventions.



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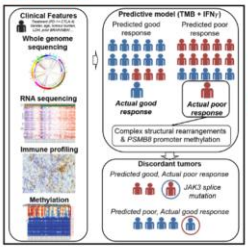
Multi-omics-based Biomarkers

Cancer Cell
Article

Multiomic profiling of checkpoint inhibitor-treated melanoma: Identifying predictors of response and resistance, and markers of biological discordance

Graphical abstract



Authors
Felicity Newell, Ines Pires da Silva, Peter A. Johansson, ..., Richard A. Scolyer, Nicola Waddell, Georgina V. Long

Correspondence
georgina.long@melanoma.org.au

In brief

Newell et al. used clinical features and multiomic analysis (WGS, RNAseq, immunohistochemistry, methylation) to show that IFNγ plus TMB most accurately predicted response to immunotherapy, but not resistance. No common mechanism of resistance was identified in keeping with tumor heterogeneity, and patients with clinical and molecular discordance were analyzed individually.

Highlights

- Multiomic analysis predicts response but not resistance to immunotherapy
- Nonresponders had no common mechanisms of resistance
- Structural rearrangements and PSMB8 promoter methylation occurred in nonresponders
- JAK3 mutation was a possible resistance mechanism in a patient predicted to respond

Newell et al., 2022, Cancer Cell 40, 88–102
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https://doi.org/10.1016/j.ccell.2021.11.012
CellPress

CANCER IMMUNOTHERAPY

Gut microbiome modulates response to anti-PD-1 immunotherapy in melanoma patients

V. Gopalakrishnan,[1,2,*] C. N. Spencer,[2,3,*] L. Nezi,[2,*] A. Reuben,[1] M. C. Andrews,[1] T. V. Karpinets,[3] P. A. Prieto,[1] D. Vicente,[1] K. Hoffman,[4] S. C. Wei,[2] A. P. Cogdill,[1,5] L. Zhao,[3] C. W. Hudgens,[6] D. S. Hutchinson,[7] T. Manzo,[2] M. Petaccia de Macedo,[6] T. Cotechini,[8] T. Kumar,[9] W. S. Chen,[9] S. M. Reddy,[10] R. Szczepaniak Sloane,[1] J. Galloway-Pena,[11] H. Jiang,[1] P. L. Chen,[12] E. J. Shpall,[13] K. Rezvani,[14] A. M. Alousi,[14] R. F. Chemaly,[15] S. Shelburne,[3,15] L. M. Vence,[2] P. C. Okhuysen,[16] V. B. Jensen,[16] A. G. Swennes,[7] F. McAllister,[18] E. Marcelo Riquelme Sanchez,[19] Y. Zhang,[14] E. Le Chatelier,[21] L. Zitvogel,[19] N. Pons,[21] J. L. Austin-Breneman,[1] L. E. Haydu,[1] E. M. Burton,[1] J. M. Gardner,[2] E. Sirmans,[17] J. Hu,[20] A. J. Lazar,[6,8] T. Tsujikawa,[6] A. Diab,[17] H. Tawbi,[17] I. C. Glitza,[17] W. J. Hwu,[17] S. P. Patel,[17] S. E. Woodman,[17] R. N. Amaria,[17] M. A. Davies,[17] J. E. Gershenwald,[2] P. Hwu,[17] J. E. Lee,[1] J. Zhang,[3] L. M. Coussens,[6] Z. A. Cooper,[1,*] P. A. Futreal,[3] C. R. Daniel,[6,3] N. J. Ajami,[7] J. F. Petrosino,[7] M. T. Tetzlaff,[6,9] P. Sharma,[2,10] J. P. Allison,[2] R. R. Jenq,[2] J. A. Wargo[1,2] ✉,*,+

Preclinical mouse models suggest that the gut microbiome modulates tumor response to checkpoint blockade immunotherapy; however, this has not been well-characterized in human cancer patients. Here we examined the oral and gut microbiome of melanoma patients undergoing anti–programmed cell death 1 protein (PD-1) immunotherapy ($n = 112$). Significant differences were observed in the diversity and composition of the patient gut microbiome of responders versus nonresponders. Analysis of patient fecal microbiome samples ($n = 43$, 30 responders, 13 nonresponders) showed significantly higher alpha diversity ($P < 0.01$) and relative abundance of bacteria of the Ruminococcaceae family ($P < 0.01$) in responding patients. Metagenomic studies revealed functional differences in gut bacteria in responders, including enrichment of anabolic pathways. Immune profiling suggested enhanced systemic and antitumor immunity in responding patients with a favorable gut microbiome as well as in germ-free mice receiving fecal transplants from responding patients. Together, these data have important implications for the treatment of melanoma patients with immune checkpoint inhibitors.

& Microbiome

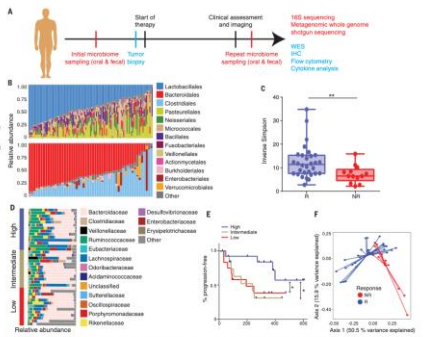

Fig. 1. Higher gut microbiome diversity is associated with improved response to anti–PD-1 immunotherapy in patients with metastatic melanoma. (A) Schema of sample collection and analyses. (B) Stacked bar plot of phylogenetic composition of common bacterial taxa (>0.2% abundance) at the order level in oral ($n = 109$, top) and fecal ($n = 53$, bottom) samples by 16S rRNA sequencing. (C) Inverse Simpson diversity scores of the gut microbiome in R ($n = 30$) and NR ($n = 13$) to anti–PD-1 immunotherapy by Mann-Whitney U rank sum (MW) test. Error bars represent the distribution of diversity scores. (D) Phylogenetic composition of fecal samples ($n = 39$) at the family level (>0.3% abundance) at baseline. High (blue, >1163 (inverse Simpson score)), $n = 13$), intermediate (gold, 746 to 1163, $n = 13$), and low (red, <746, $n = 13$) diversity groups were determined using tertiles of inverse Simpson scores. (E) Kaplan-Meier (KM) plot of PFS by fecal diversity: high (median PFS undefined), intermediate (median PFS = 232 days), and low (median PFS = 188 days). High versus intermediate diversity (HR 3.62, 95% CI 1.02 to 12.74) and high versus low (HR 3.52 95% CI 1.02 to 12.52) by univariate Cox model. (F) Principal coordinate analysis of fecal samples ($n = 43$) by response using weighted UniFrac distances. *$P < 0.05$, **$P = 0.01$.

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Gene Signatures across Multiple IO Data Sets

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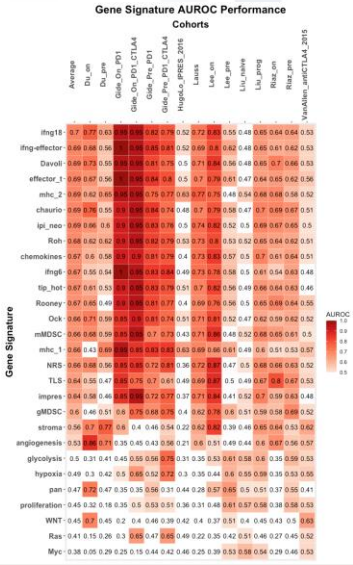
DOI: 10.1002/mc.23442

RESEARCH ARTICLE

Molecular Carcinogenesis WILEY

Systematic evaluation of the predictive gene expression signatures of immune checkpoint inhibitors in metastatic melanoma

Samuel Coleman[1] | Mengyu Xie[1] | Ahmad A. Tarhini[2,3] | Aik Choon Tan[1]



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Correlation of Gene Signatures (28 signatures)

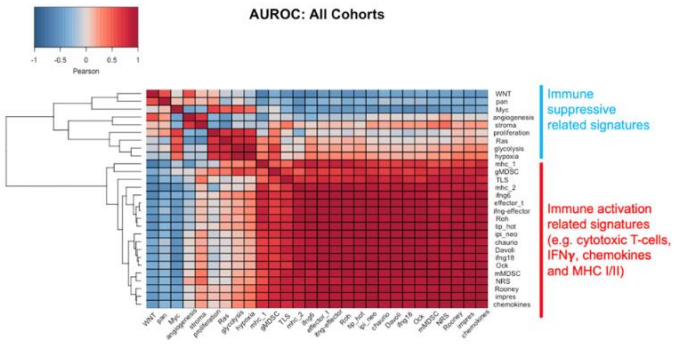

FIGURE 2 Correlation of the 28 predictive gene signatures. Pearson's correlation of the 28 predictive gene signatures across all 15 cohorts based on AUROC. The heatmap illustrated the two clusters, the "immune active" and the "immune suppressive" clusters. AUROC, area under the receiver operating curve. [Color figure can be viewed at wileyonlinelibrary.com]

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(Coleman, Xie, Tarhini, Tan ***Mol Carcinog***, 2023)

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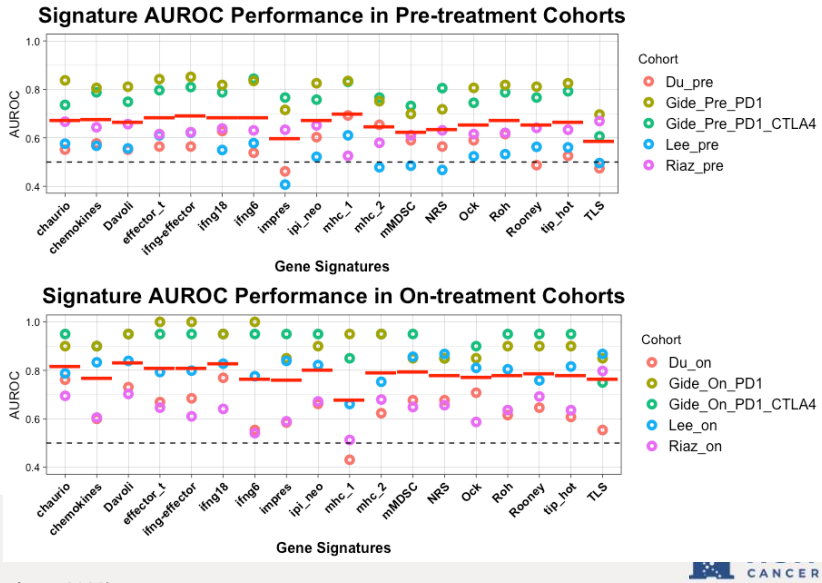
Predictive Signatures in Pre- and On-Treatment Cohorts



(Coleman, Xie, Tarhini, Tan ***Mol Carcinog***, 2023)

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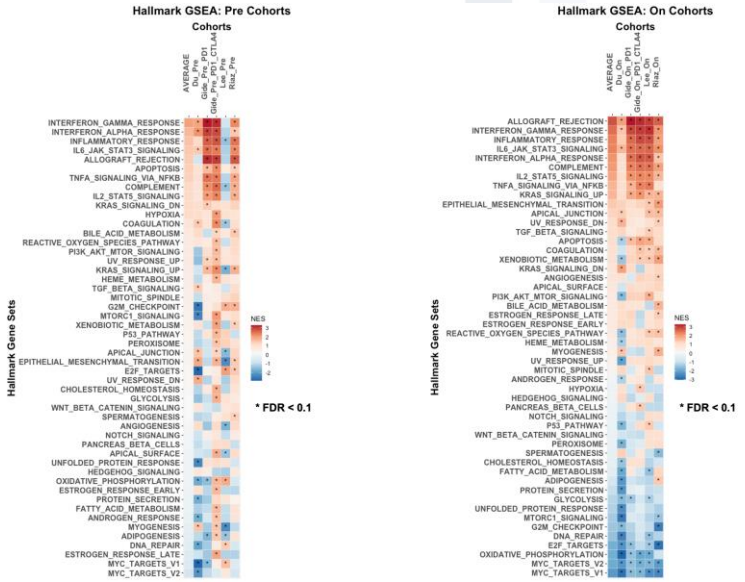
GSEA results in Pre- and On-treatment Cohorts



(Coleman, Xie, Tarhini, Tan ***Mol Carcinog***, 2023)

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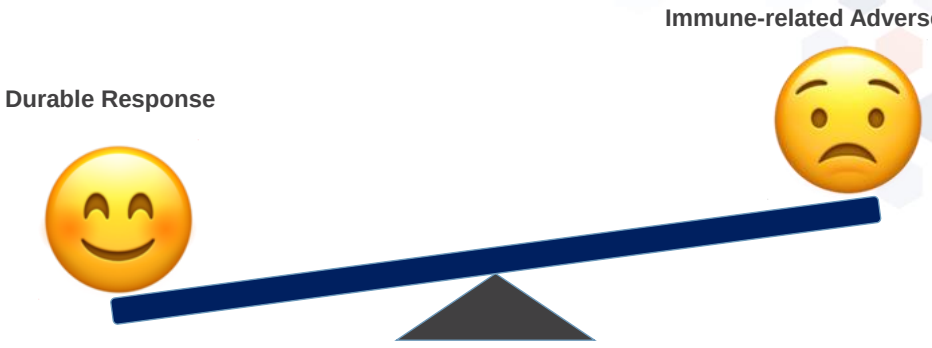
Balancing Act Between Response and Adverse Events



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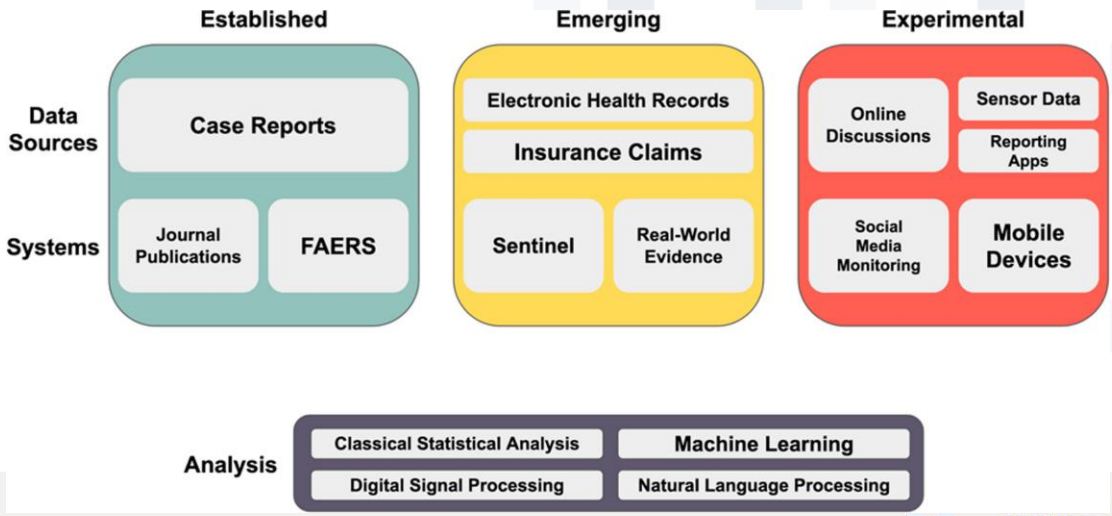
Spectrum of Real-World Data



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(Lavertu et al, ***CP&T*** 2021)

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Immune-related Adverse Events (irAE)

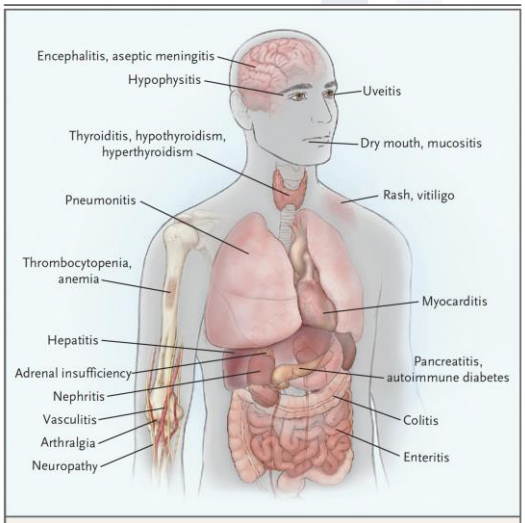

Figure 1. Organs Affected by Immune Checkpoint Blockade.
Immune checkpoint blockade can result in inflammation of any organ. Shown are the most common immune-related adverse events that clinicians encounter in patients treated with immune checkpoint blockade.

(Postow et al, ***NEJM*** 2018)

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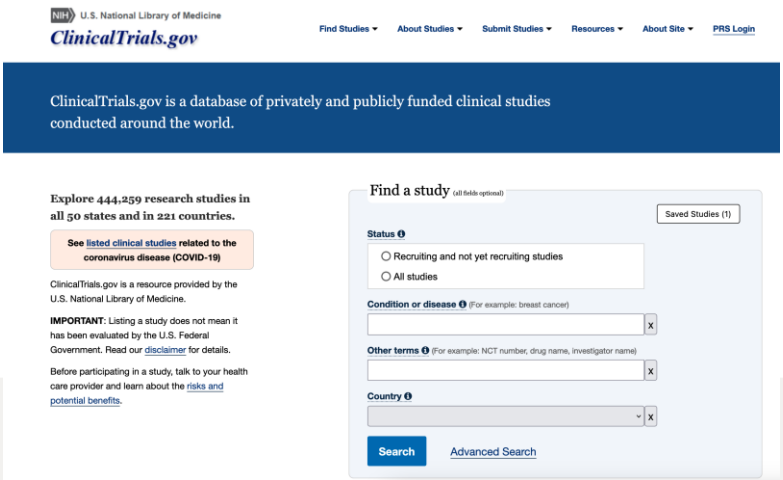
Mining large scale clinical data from ClinicalTrials.gov



- ClinicalTrials.gov is a database of publicly and privately supported clinical studies of human participants conducted around the world

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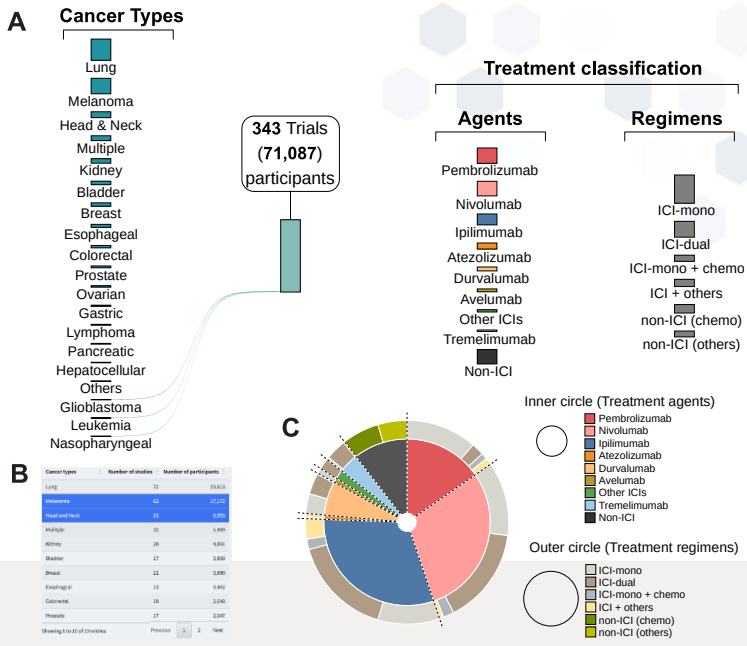

(Fadlullah MZH et al, ***The Oncologist*** 2024)

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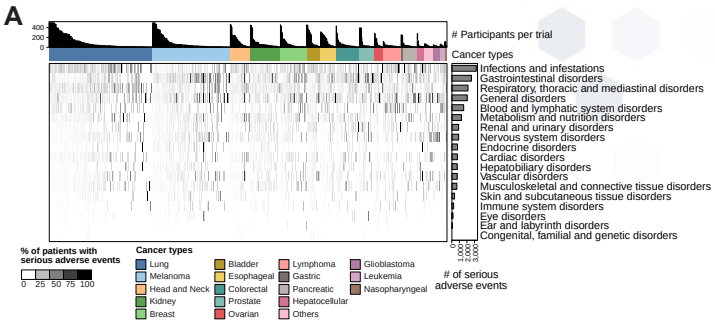

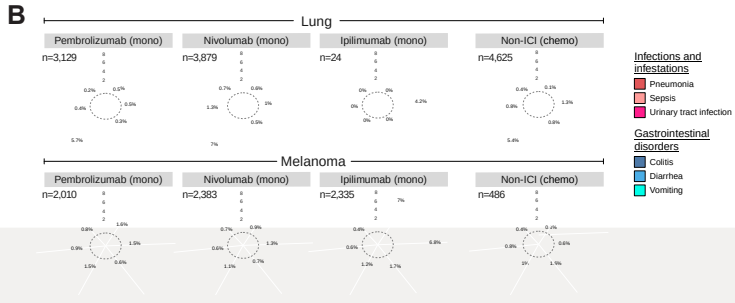

(Fadlullah MZH et al, ***The Oncologist*** 2024)

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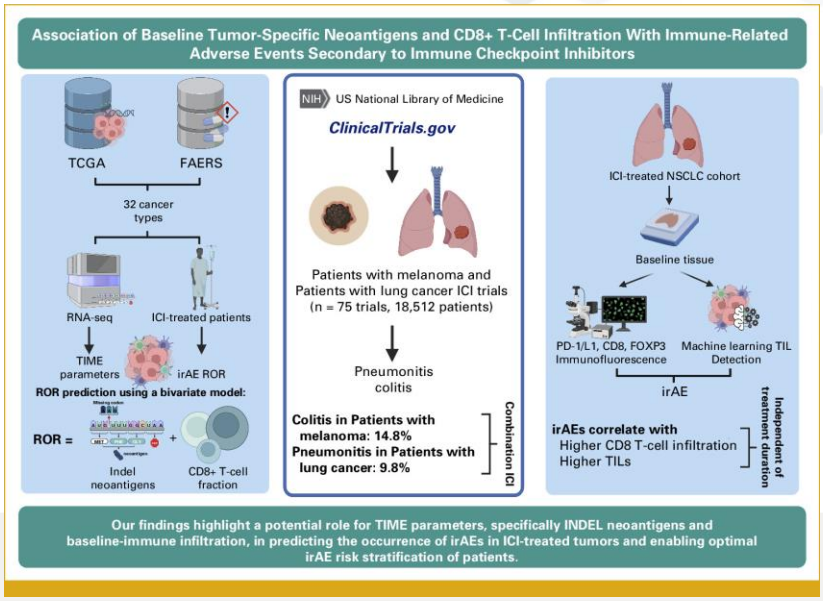
Mining FAERS and Linking TCGA Molecular Data



(Kerepesi et al, ***JCO Precision Oncology*** 2024)

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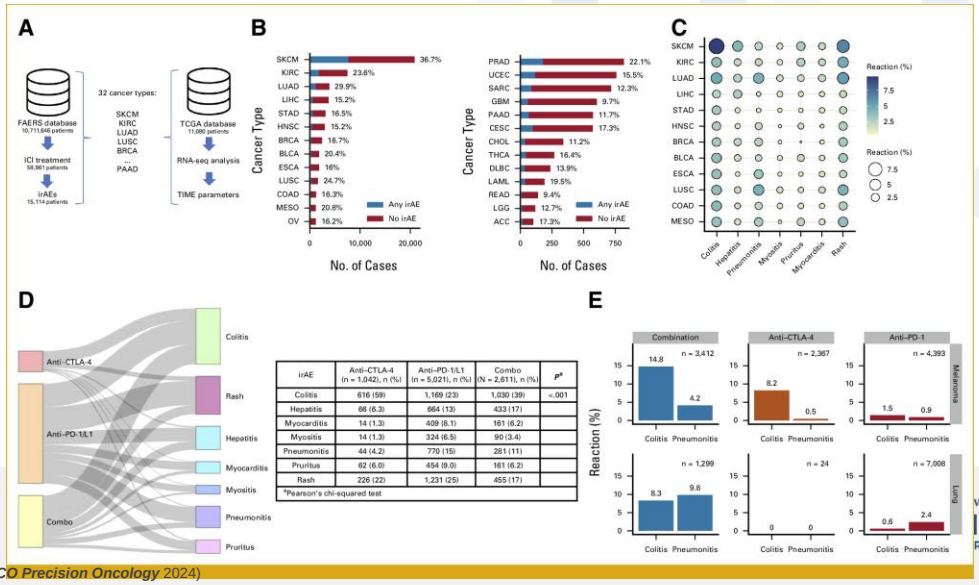
Mining FAERS and Linking TCGA Molecular Data



irAE	Anti-CTLA-4 (n = 1,042), n (%)	Anti-PD-1/L1 (n = 5,021), n (%)	Combo (N = 2,611), n (%)	P*
Colitis	616 (59)	1,169 (23)	1,030 (39)	<.001
Hepatitis	66 (6.3)	664 (13)	433 (17)	
Myocarditis	14 (1.3)	409 (8.1)	161 (6.2)	
Myositis	14 (1.3)	324 (6.5)	90 (3.4)	
Pneumonitis	44 (4.2)	770 (15)	281 (11)	
Pruritus	62 (6.0)	454 (9.0)	161 (6.2)	
Rash	226 (22)	1,231 (25)	455 (17)	

*Pearson's chi-squared test

(Kerepesi et al, ***JCO Precision Oncology*** 2024)

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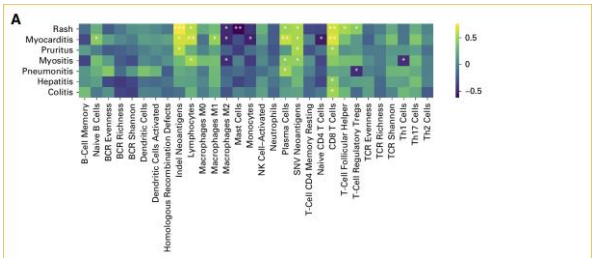
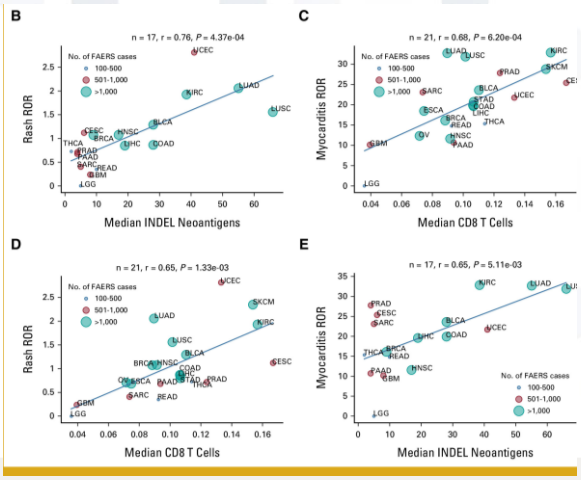
Mining FAERS and Linking TCGA Molecular Data





(Kerepesi et al, ***JCO Precision Oncology*** 2024)

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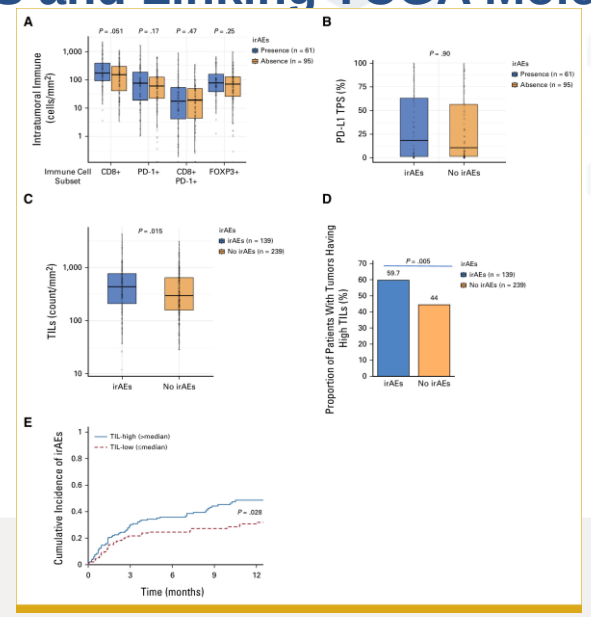
Mining FAERS and Linking TCGA Molecular Data



(Kerepesi et al, ***JCO Precision Oncology*** 2024)

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Acknowledgements

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Zaki Wilmot, Ph.D.
Min Hu
Li Li, Ph.D.
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David Stone
Ching-Nung Lin, Ph.D.
Sam Coleman

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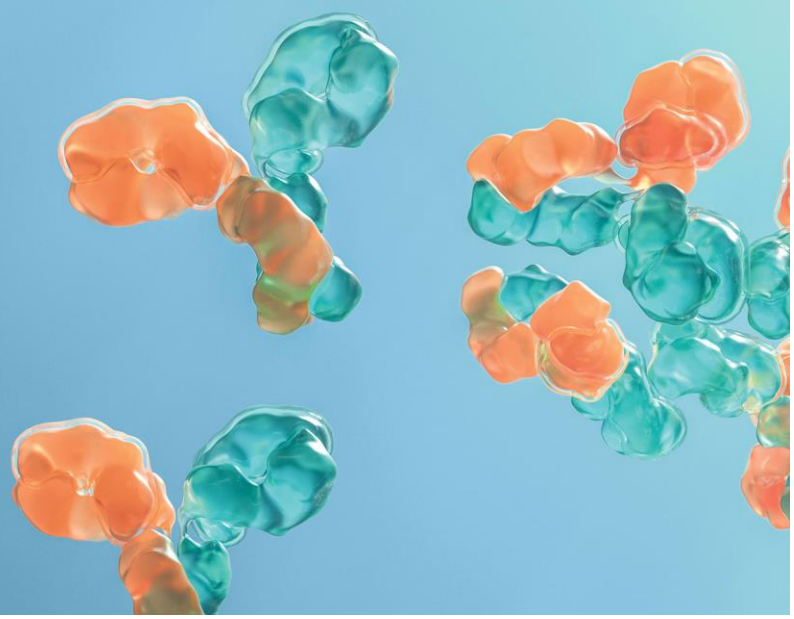
Role of Big data in I/O Therapies



Hisham Hamadeh

SVP, Global Head of Data Science & AI

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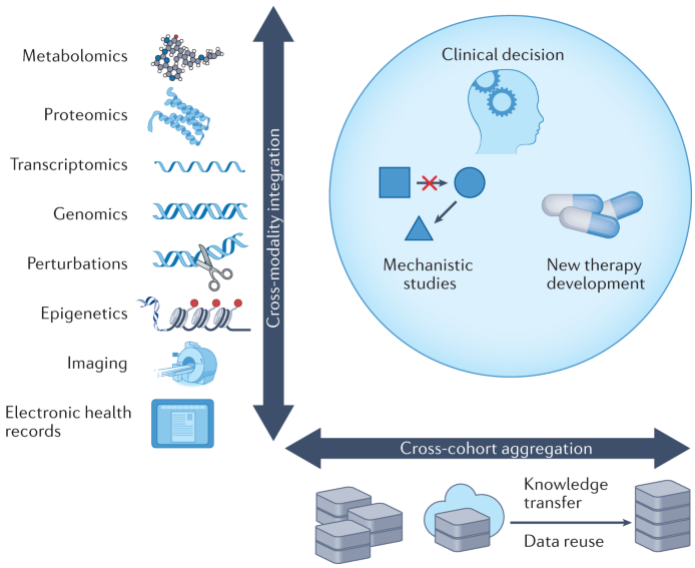

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Jiang et al., 2022 Nature

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FAIR Data is Becoming Increasingly Important

Data is easy to find by colleagues (and machines). Metadata

Data is available to colleagues (and machines) who need it in an intuitive interface

Data can be readily combined with other data and used by a variety of systems

Data can be re-used for a variety of purposes often unimagined by the originator

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FAIRification is the responsibility of ALL

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Volume 83, Issue 8

15 April 2023

CANCER RESEARCH | REVIEW

Case Studies for Overcoming Challenges in Using Big Data in Cancer

Shawn M. Sweeney[1], Hisham K. Hamadeh[2], Natalie Abrams[3], Stacey J. Adam[4], Sara Brenner[5], Dana E. Connors[4], Gerard J. Davis[6], Louis D. Fiore[7], Susan H. Gawel[6], Robert L. Grossman[8], Sean E. Hanlon[9], Karl Hsu[10], Gary J. Kelloff[11], Ilan R. Kirsch[12], Bill Louv[13], Deven McGraw[14], Frank Meng[15], Daniel Milgram[16], Robert S. Miller[17], Emily Morgan[4], Lata Mukundan[16], Thomas O'Brien[18], Paul Robbins[18], Eric H. Rubin[19], Wendy S. Rubinstein[5], Liz Salmi[20], Teilo H. Schaller[13], George Shi[6], Caroline C. Sigman[15], and Sudhir Srivastava[21]

CANCER RESEARCH | REVIEW

Challenges to Using Big Data in Cancer

Shawn M. Sweeney[1], Hisham K. Hamadeh[2], Natalie Abrams[3], Stacey J. Adam[4], Sara Brenner[5], Dana E. Connors[4], Gerard J. Davis[6], Louis Fiore[7], Susan H. Gawel[6], Robert L. Grossman[8], Sean E. Hanlon[9], Karl Hsu[10], Gary J. Kelloff[11], Ilan R. Kirsch[12], Bill Louv[13], Deven McGraw[14], Frank Meng[15], Daniel Milgram[16], Robert S. Miller[17], Emily Morgan[4], Lata Mukundan[16], Thomas O'Brien[18], Paul Robbins[18], Eric H. Rubin[19], Wendy S. Rubinstein[5], Liz Salmi[20], Teilo Schaller[13], George Shi[6], Caroline C. Sigman[15], and Sudhir Srivastava[21]

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Recommendations to Ensure Success of Big Data in Oncology

Data Operability, Interoperability, and quality are critical
- Adhere to published guidelines on building interoperable datasets
- Use data-sharing taxonomy – size, data elements, PHI, static or longitudinal

Reducing time/effort to aggregate data
- Work processes with cloud-based stacks
- Integrate data aggregation into workflows
- Incorporate QA/QC throughout work processes
- Use federated systems to improve the efficiency of data aggregation

Collect data with intent to share from the outset
- Encourage initiatives and collaborations to foster data sharing by the research community
- Require data beyond primary clinical phenotype from EHRs, e.g., molecular, digital histopathology, DICOM, insurance claims, prescription refill, and patient-reported outcomes data.

Patient Privacy
- Adopt well-thought-out open data-sharing models that include data privacy regulations and practices, data cycle management, and account for/control data reanalyses
- Broad consent to enable research-ready databases

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Data Source	Size
GDC – The University of Chicago, NCI Center for Cancer Genomics	84,609 cases from 68 projects
Million Veteran Program	690,000 Participants
CancerLinQ	2,000,000+ patients
AACR Project GENIE	111,222 patients
Project Data Sphere	240,000+ patients

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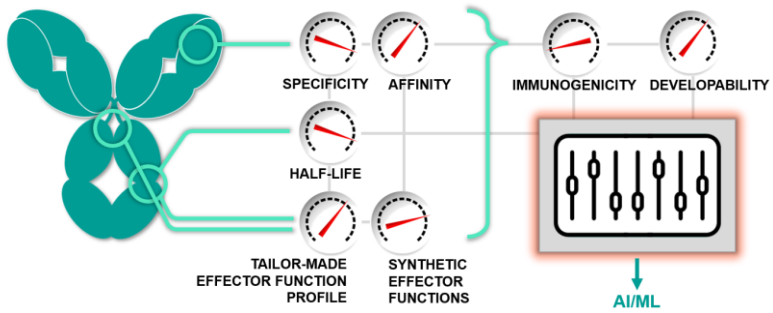
Turn Antibody Design into a Predominantly Digital Exercise

A strategic investment for Genmab to remain the world's best antibody company



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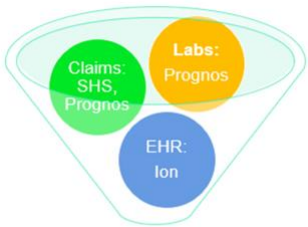
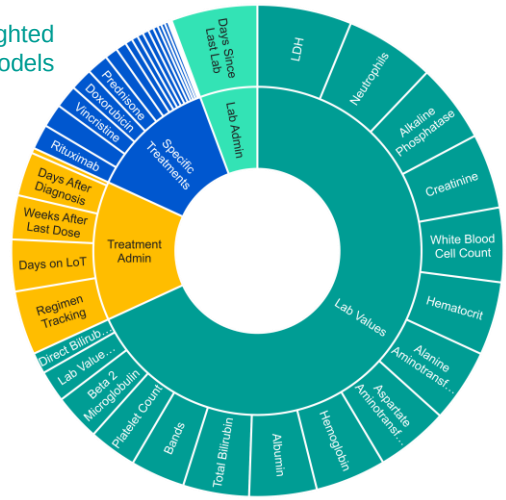
Health Equity and Precision Targeting of Patients/HCPs

>60% of cancer care happens in the community setting

Integrate numerous data sources



Build weighted predictive models



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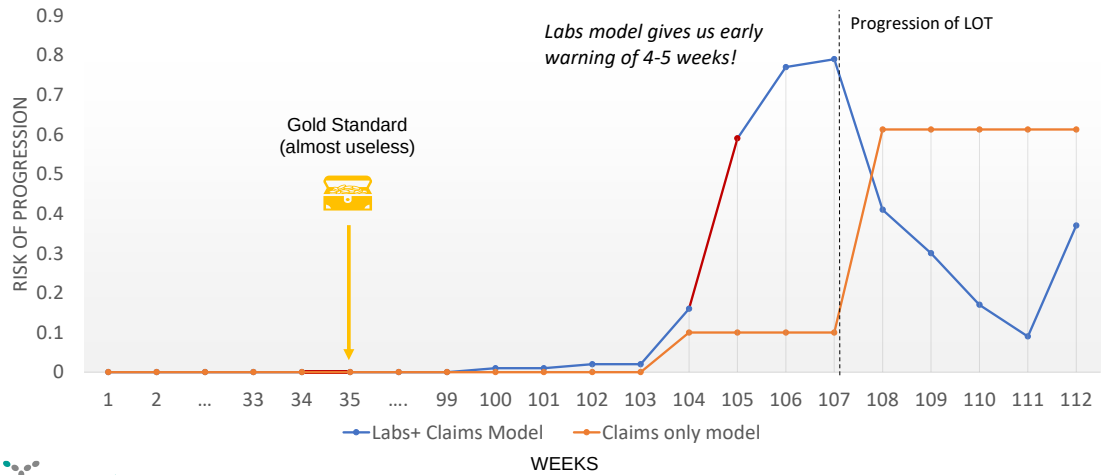
AI models treat each patient as its own cohort

This approach enables the identification of patients that are eligible for Genmab medicines



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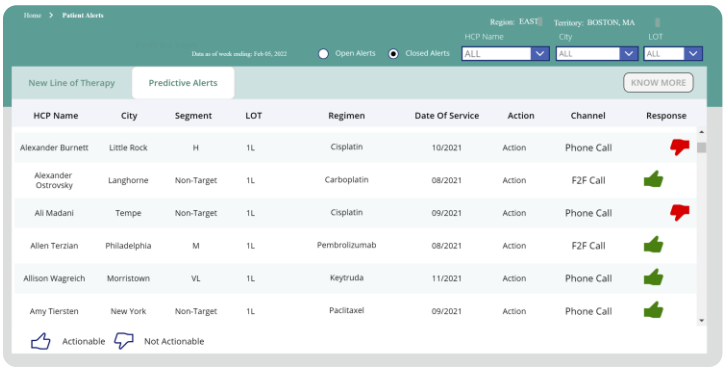
Engagement with the field force



"Subject:
Alerts: super helpful!"

"We may not have found him as quickly if not for this alert system"

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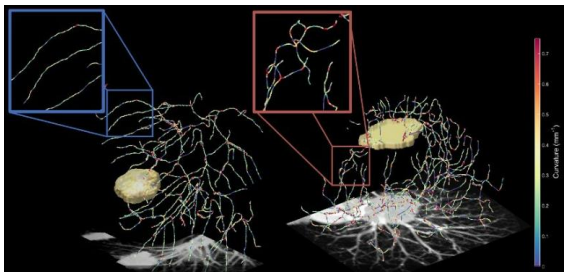
Computer Vision (AI) generates new scientific insights for response prediction

ScienceAdvances 2023

A tumor vasculature–based imaging biomarker for predicting response and survival in patients with lung cancer treated with checkpoint inhibitors



97 AI-driven measurements on CT scans

shape & structure of tumor vasculature network including branching, torsion, curvature and vessel volume

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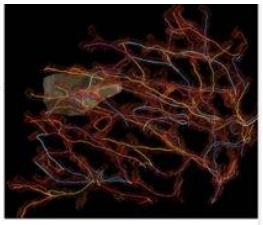
Baseline features correlate with tumor size change



AI is revealing new useful non-invasive variables that are **not humanly calculable**

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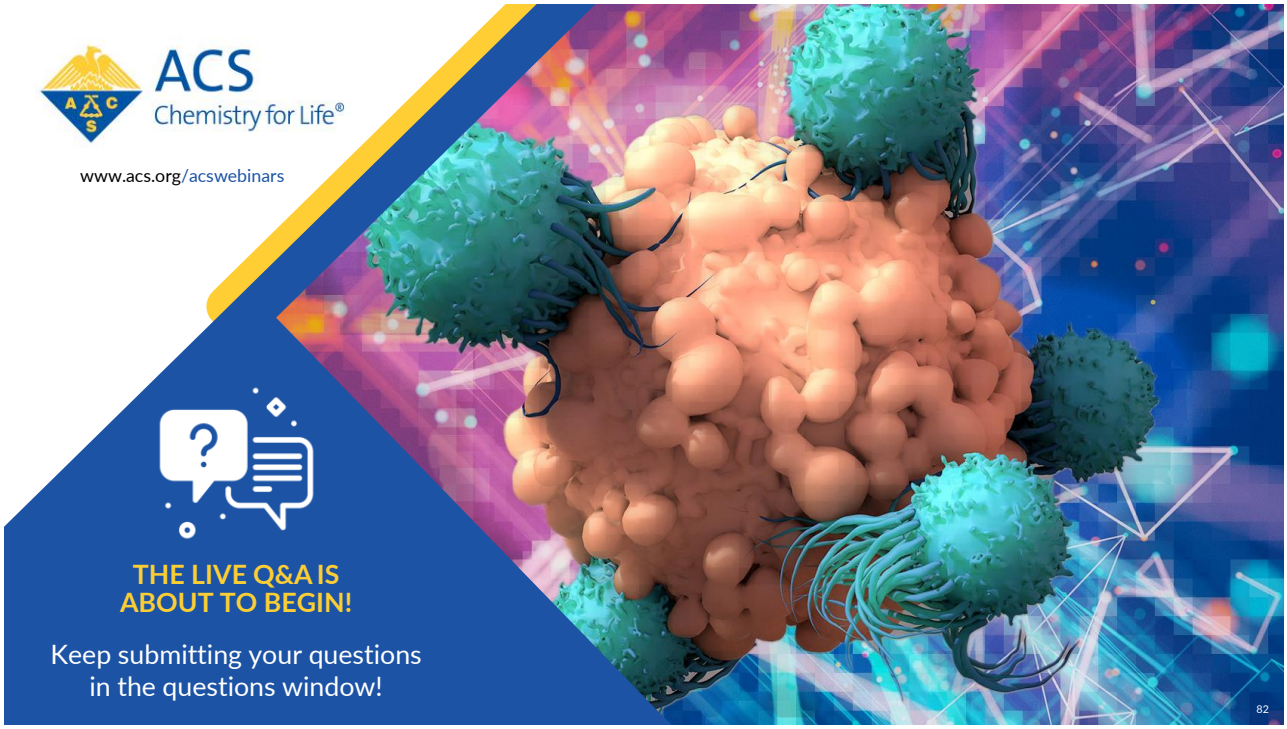
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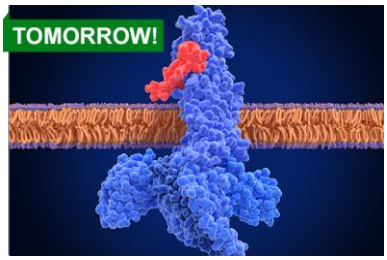

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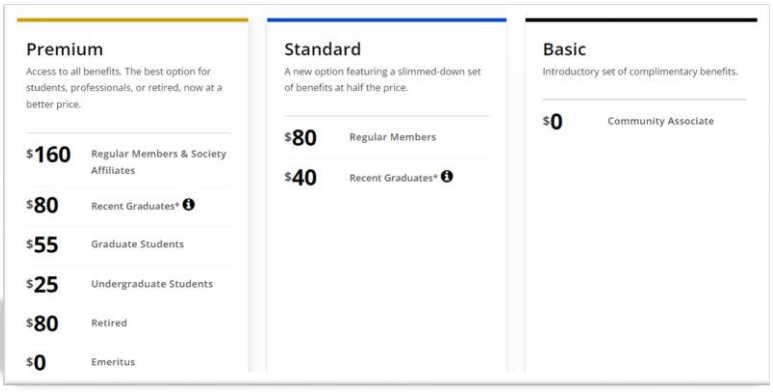

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