

ASCO[®]

AMERICAN SOCIETY OF CLINICAL ONCOLOGY
ASSOCIATION FOR CLINICAL ONCOLOGY
KNOWLEDGE CONQUERS CANCER

Evidence Generation to Inform Oncology Care

Practice-Changing Research Since the IOM 2013 Report

Julie Gralow, MD, FASCO, FACP
Chief Medical Officer, ASCO

October 6, 2023

Practice-Changing Research Since the IOM 2013 Report

Precision Medicine

New drugs and treatment approaches

De-escalation of therapy

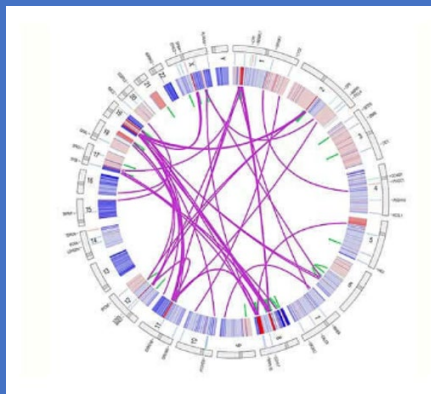
Focus on toxicities and impact of treatment on the patient

Equity, diversity, and inclusion

COVID-19 pandemic-related changes

Innovations in clinical trials design


Precision Medicine



The Cancer Genome Atlas

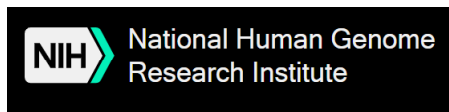
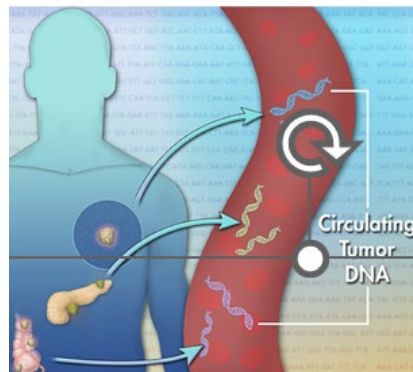
NATIONAL ACADEMIES Sciences Engineering Medicine 2023

Realizing the Potential of Genomics across the Continuum of Precision Health Care



Proceedings of a Workshop

Circulating tumor DNA: A new generation of cancer biomarkers



Liquid Biopsies

This Issue Views 2,604 | Citations 9 | Altmetric 39

Editorial

February 25, 2021

Precision Medicine in Oncology—Toward the Integrated Targeting of Somatic and Germline Genomic Aberrations

Timothy A. Yap, MBBS, PhD^{1,2}; Amber Johnson, PhD²; Funda Meric-Bernstam, MD^{1,2}

» Author Affiliations

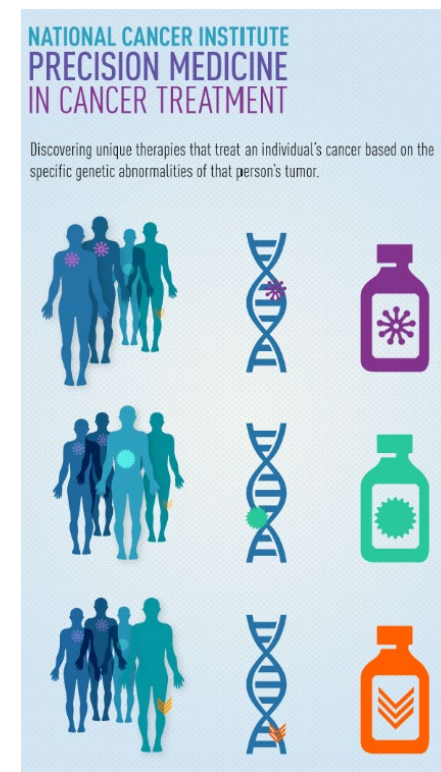
JAMA Oncol. 2021;7(4):507-509. doi:10.1001/jamaoncol.2020.7988

Next Gen Sequencing



NATIONAL CANCER INSTITUTE
PRECISION MEDICINE
IN CANCER TREATMENT

Discovering unique therapies that treat an individual's cancer based on the specific genetic abnormalities of that person's tumor.



Somatic Genomic Testing in Patients With Metastatic or Advanced Cancer

ASCO Provisional Clinical Opinion

- Patients with metastatic cancer should undergo genomic sequencing if presence of ≥ 1 genomic alteration has regulatory approval to guide use of (or exclusion from) treatments
- **Multigene panel-based assays** should be used if >1 biomarker-linked therapy is approved for the patient's disease
- **Site-agnostic approvals** for any cancer with high TMB, MMR deficiency, NTRK fusions, *RET fusions**, *BRAF V600E mutations**, *FGFR alterations** **provide a rationale for genomic testing for all solid tumors**

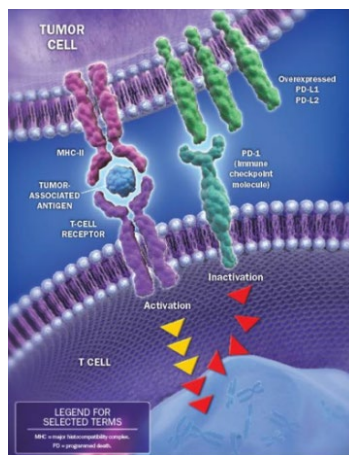
Chakravarty D et al. JCO 40:1231-1258, 2022

*Approved post publication

Anticancer Drug Approvals in the Past Decade—Quality vs Quantity

Rajshekhar Chakraborty, MD

New Drugs and Treatment Approaches



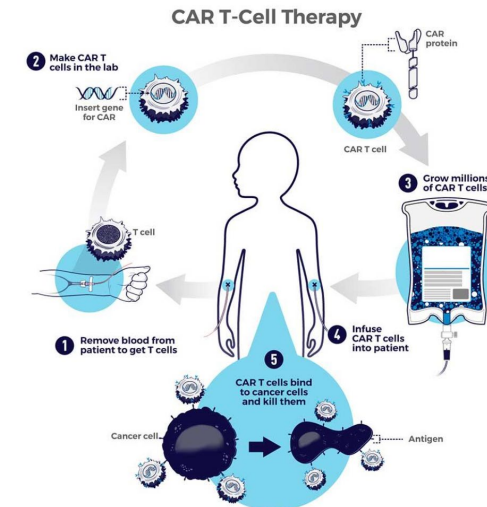
Immune Checkpoint Inhibitors

Targeted Therapies



Targeted therapy treats cancer by targeting proteins that control how cancer cells grow, divide, and spread.

Credit: National Cancer Institute



CAR T-cell therapy is a type of treatment in which a patient's T cells are genetically engineered in the laboratory so they will bind to specific proteins (antigens) on cancer cells and kill them. (1) A patient's T cells are removed from their blood. Then, (2) the gene for a special receptor called a chimeric antigen receptor (CAR) is inserted into the T cells in the laboratory. The gene encodes the engineered CAR protein that is expressed on the surface of the patient's T cells, creating a CAR T cell. (3) Millions of CAR T cells are grown in the laboratory. (4) They are then given to the patient by intravenous infusion. (5) The CAR T cells bind to antigens on the cancer cells and kill them.

cancer.gov

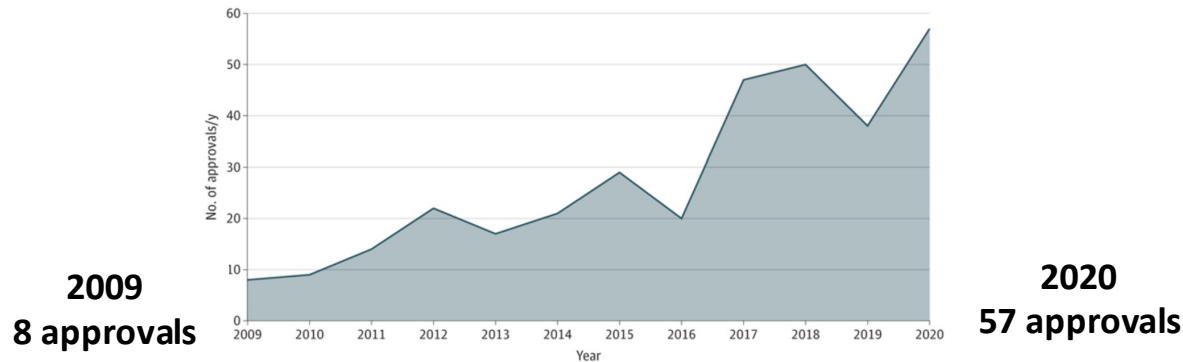
CAR-T Cell Therapy



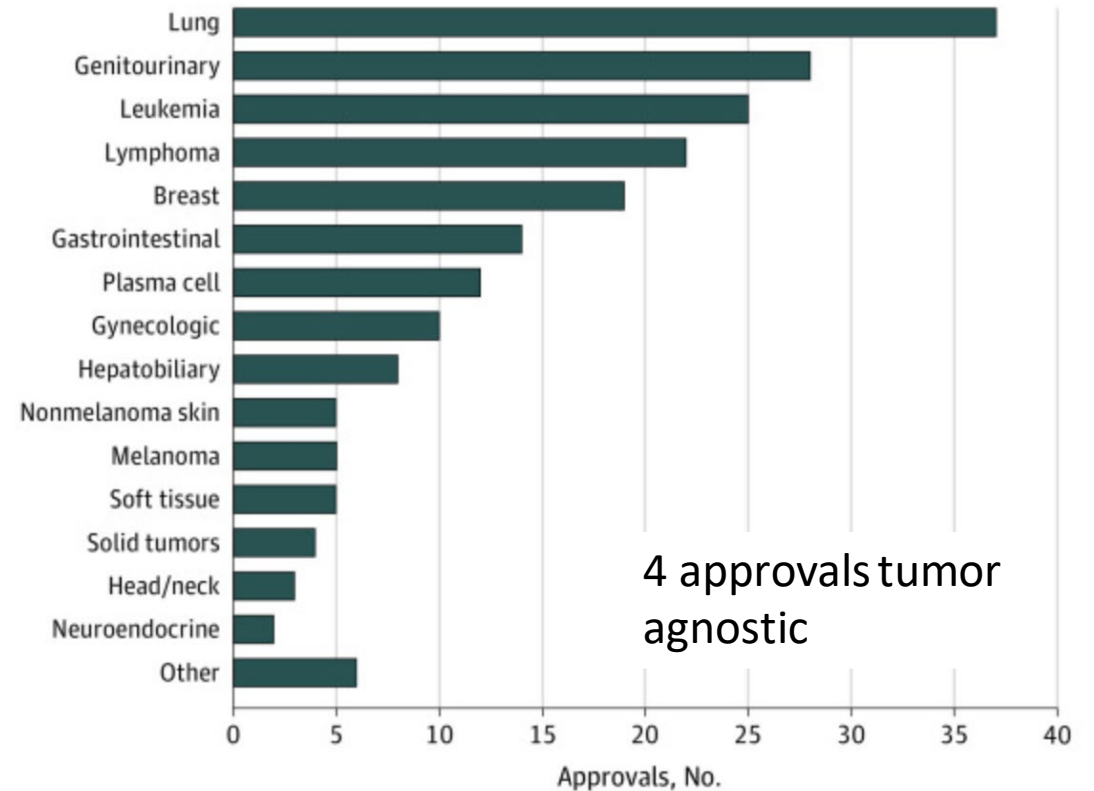
Antibody-drug Conjugates

Anticancer Drugs Approved by FDA 2009-2020 by Mechanism of Action

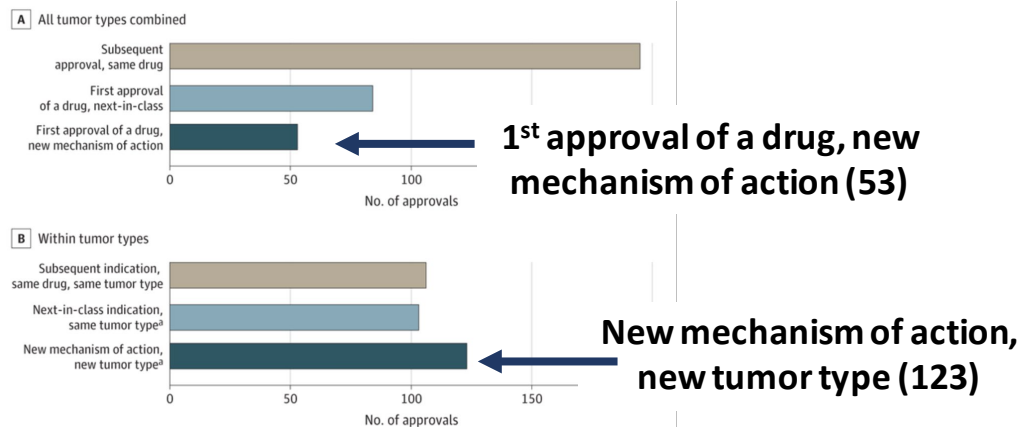
Total # Anticancer Drugs Approved by FDA



Number of FDA Oncologic Approvals Between 2016-2021 by Tumor Organ System (n=207)



Mechanism of Action of 332 Anticancer Drug Approvals 2009-2020



Benjamin DJ et al, JAMA Netw Open. 2022 Mar; 5(3): e222265

Olivier T et al, JAMA Netw Open 2021;4(12):e2138793

'Less is more' approach is changing cancer treatment for some patients

The New York Times

By Jacqueline Howard, CNN
Published 6:53 AM EDT, Wed July 5, 2023

Rectal Cancer Patients Could Be Spared the Effects of Radiation

A large "de-escalation" trial suggests that tens of thousands of people annually may be able to rely on only chemotherapy and surgery to treat their illness.

Less Radiation

Meeting Coverage > ASCO

De-Escalated Surgery Suffices for Low-Risk Cervical Cancer

— Simple hysterectomy non-inferior to radical operation

by Ed Susman, Contributing Writer, MedPage Today June 2, 2023

Less Surgery

De-escalation of Therapy

BREAST CANCER

Tens of Thousands of Early Breast Cancer Patients May Not Need Chemo After All

TAILORx: Many Women With Early Breast Cancer Can Avoid Chemotherapy

Cancer Therapy Advisor

Less Chemo

June 28, 2023

ASCO 2023: Treatment De-Escalation and the Role of Age in HER2+ Breast Cancer

Alan P. Lyss, MD

De-escalation of Therapy

Using less aggressive or less toxic treatment while maintaining or improving therapeutic outcomes

Systemic Therapy

- **Advances in genomics and molecular profiling**
 - Multigene assays to determine which early-stage breast cancer patients do not benefit from chemotherapy
 - Targeted therapies
- **Use of neoadjuvant therapy response**
 - Pathologic Complete Response (pCR) to determine post-op therapy

Surgery

- **Minimally Invasive Surgery**
 - Robotic and laparoscopic surgical techniques - improved precision and reduced invasiveness
- **Organ Preservation**
 - Functional preservation of breast, rectum, larynx, etc

Radiation Therapy

- **Intensity-Modulated Radiation Therapy**
- **Hypofractionation**
- **Stereotactic body radiation therapy (SBRT)**

Focus On Toxicities and Impact of Treatment on the Patient



Symptoms, Quality of Life, PROs, Financial and Time Toxicity, Survivorship

Patient-Reported Outcomes PROs

- ✓ Health-related quality of life (HRQOL)
- ✓ Symptoms
- ✓ Function
- ✓ Satisfaction with care or symptoms
- ✓ Adherence to prescribed medications or other therapy
- ✓ Perceived value of treatment

CAREER

Dealing with "Time Toxicity" in Cancer Treatment

Suggestions for those frustrated about the amount of time spent in treatment.

Easing the Load: The Heavy Burden of Financial Toxicity on Cancer Patients

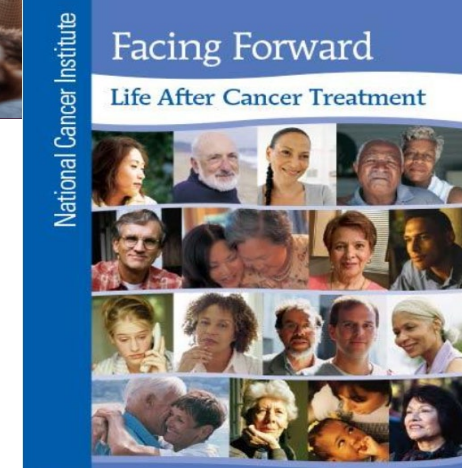
By Bobby Green, MD
President and Chief Medical Officer, Thyme Care



Journal of Clinical Oncology[®]
An American Society of Clinical Oncology Journal

New drug classes = new toxicities

Management of Immune-Related Adverse Events in Patients Treated With Immune Checkpoint Inhibitor Therapy: ASCO Guideline Update *Schneider BJ et al, JCO 2021*



Cancer Survivorship

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Equity, Diversity, and Inclusion

ASCO
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ASCO's Equity, Diversity, and Inclusion Action Plan

A Legacy of Commitment, A Future of Promise for All Individuals with Cancer

Visit asco.org/equity to learn more.

Cancer Disparities and Health Equity: A Policy Statement From the American Society of Clinical Oncology *Patel MI et al, JCO 2020*

Meeting Coverage > ASCO

Medicaid Expansion Tied to Better Outcomes in Black Patients With GI Cancers

— Two-year mortality decreased for three types of GI cancer in expansion vs non-expansion states

by Charles Bankhead, Senior Editor, MedPage Today May 25, 2023

The State of Cancer Disparities in the United States

ACS reports on racial/ethnic and socioeconomic disparities in cancer occurrence, programs that target cancer disparities, and policy recommendations.



NCI Equity and Inclusion Program

NATIONAL ACADEMIES Sciences Engineering Medicine
2021
Promoting Health Equity in Cancer Care
Proceedings of a Workshop

ASCO
American Society of Clinical Oncology

Strategic Plan for INCREASING RACIAL & ETHNIC DIVERSITY in the Oncology Workforce

2022 SNAPSHOT
State of the Oncology Workforce in America
STATE OF CANCER CARE IN AMERICA

UNDERREPRESENTED IN MEDICINE

- 4.7% Oncologists are Hispanic or Latino¹
- 3% Oncologists are Black or African American¹
- 0.1% Oncologists are American Indian or Alaska Native²

WOMEN IN ONCOLOGY

- 35.8% Oncologists are female⁵

GEOGRAPHY

- 10.5% Oncologists practice in a rural area^{6,8}

COVID-19 Pandemic- related Changes

Cancer Therapy Advisor

September 18, 2023

Cancer Deaths Increased During the First 2 Years of the COVID-19 Pandemic



Telehealth-Based Cancer Care Surged during COVID. Will It Continue?



Appointments with health care providers via video and phone calls, known as telehealth, increased dramatically during the COVID pandemic.
Credit: iStock

ASCO Road to Recovery Report: Learning From the COVID-19 Experience to Improve Clinical Research and Cancer Care Pennell NA et al. J Clin Oncol, 2020



ASCO Road to Recovery Report Recommendations: Cancer Care Delivery Goals



- 1** Promote and Protect Equitable Access to High-quality Cancer Care
- 2** Support Safe Delivery of High-Quality Cancer Care
- 3** Advance Policies to Ensure Oncology Providers Have Sufficient Resources to Provide High-Quality Patient Care
- 4** Recognize and Address Threats to Clinician, Provider, and Patient Well-Being
- 5** Improve Patient Access to High-Quality Cancer Care via Telemedicine

Pennell, Dillmon, Levit, et al. [American Society of Clinical Oncology Road to Recovery Report: Learning from the COVID-19 Experience to Improve Clinical Research and Cancer Care](#). Journal of Clinical Oncology. 2020. 39:2, 155-169.

Broadening Eligibility Criteria to Make Clinical Trials More Representative: American Society of Clinical Oncology and Friends of Cancer Research Joint Research Statement

Edward S. Kim, Suanna S. Bruinooge, Samantha Roberts, Gwynn Ison, Nancy U. Lin, Lia Gore, Thomas S. Uldrick, Stuart M. Lichtman, Nancy Roach, Julia A. Beaver, Rajeshwari Sridhara, Paul J. Hesketh, Andrea M. Denicoff, Elizabeth Garrett-Mayer, Eric Rabin, Prañk Multani, Tatiana M. Prowell, Caroline Schenkel, Marina Kozak, Jeff Allen, Ellen Sigal, and Richard L. Schilsky



Innovations in Clinical Trial Design

- Expanded eligibility
- Patient-centric
- Decentralized
- Pragmatic design
- Umbrella and basket studies
- Real World Data



JOURNAL ARTICLE

Researcher Experience and Comfort With Telemedicine and Remote Patient Monitoring in Cancer Treatment Trials

Morgan R L Lichtenstein, Laura A Levit, Caroline Schenkel, Kelsey Kirkwood, Lola A Fashoyin-Aje, Suanna S Bruinooge, Michael J Kelley, Josh A Mailman, Allison Magnuson, Daniel P Mirda ... Show more

Facilitating Review of Real-World Data Studies: The Oncology QCARD Initiative



Just ASK™

INCREASING DIVERSITY IN CANCER CLINICAL RESEARCH
AN ACCC-ASCO TRAINING PROGRAM

ASCO

AMERICAN SOCIETY OF CLINICAL ONCOLOGY
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ACCC

Association of Community Cancer Centers

ASCO-ACCC Equity, Diversity, and Inclusion Research Site Self-Assessment

ASCO AMERICAN SOCIETY OF CLINICAL ONCOLOGY
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Can changes made during the COVID-19 pandemic be incorporated into standard clinical trials practice?

Minimizing amount of data collected

Reducing number of clinic visits and procedures

Leveraging technology – remote and automated interactions

Remote visits through telehealth

Visits and procedures at local clinics

Sending study drugs and materials to homes of participants

ASCO-Friends of Cancer Research Task Force Survey

JCO® Oncology Practice
An American Society of Clinical Oncology Journal

Sponsor Perspectives on the Impact of the COVID-19 Pandemic on Interventional Cancer Clinical Trial Protocols and Data Quality

Unger JM et al, JCO Oncol Practice 2023

CONCLUSION

- Nearly all sponsors observed a temporary increase in protocol deviations during the pandemic
- Most reported minimal/no impact on overall data integrity
- The pandemic accelerated an emerging trend toward **greater flexibility** in trial conduct, with potential benefits of **reduced burden** on trial participants and sites and **improved patient access** to research

**Evidence Generation to
Inform Oncology Care**

***Practice-Changing
Research Since the
IOM 2013 Report***

Thank You!