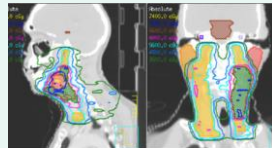


# FCDS **Florida Cancer Data System**

## What's New in Cancer Care? Classification, Diagnosis, Imaging & Treatment

1



FCDS VIRTUAL ANNUAL CONFERENCE

8/25/2022

STEVEN PEACE, CTR



1

## CDC & Florida DOH Attribution

2



“Funding for this conference was made possible (in part) by the Centers for Disease Control and Prevention. The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services, nor does the mention of trade names, commercial practices, or organizations imply endorsement by the US Government.”



FCDS would also like to acknowledge the Florida Department of Health for its support of the Florida Cancer Data System, including the development, printing and distribution of materials for the 2022 FCDS Annual Conference and the 2022-2023 FCDS Webcast Series under state contract COHAW. The findings and conclusions in this series are those of the author(s) and do not necessarily represent the official position of the Florida Department of Health.

2

# Presentation Outline

3

- Introduction
- 2022 ACS Cancer Facts & Figures - Statistics
- 2021 Annual Report to the Nation on the Status of Cancer
- Cancer Trends Progress Report – 20<sup>th</sup> Anniversary
- AACR Cancer Progress Report 2021
- NCCN Annual Report 2021
- ASCO Report on Progress Against Cancer 2021
- FDA New Drug Therapy Approvals in 2021
- New Developments in Cancer Incidence – esophagus, endometrium, pancreas
- New Developments in Cancer Screening – pancreas, lung, melanoma, MCEd Tests
- New Developments in Tumor Classification & Molecular-Biomarker Testing
- New Developments in Diagnostic Tools & Cancer Treatments – imaging, XRT, Immuno
- Update on Effects of the COVID-19 Pandemic on Cancer Diagnosis, Stage, and Treatment
- 2022 Update on Cancer Moonshot
- Questions



3

# Introduction

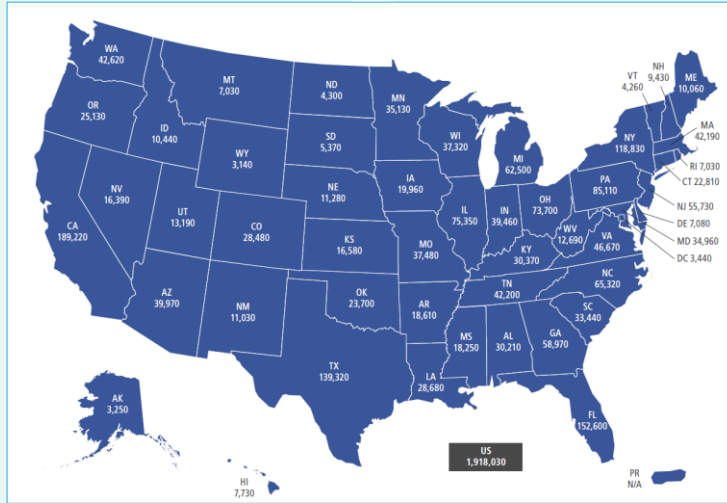
4

- The burden of cancer is growing rapidly in the United States and worldwide.
- The USPSTF updated guidelines for screening of colorectal and lung cancer –
  - Begin at 45 years for colorectal cancers
  - Begin at 50 years for lung cancer
- These changes were due to increased cancer rates in these age groups
- **Fast Facts on Cancer Health Disparities**
  - African Americans have incidence of multiple myeloma more than twice that of non-Hispanic whites
  - American Indian/Alaskan Native individuals are more than 4 times more likely to develop stomach cancer than whites
  - During 2012-2016 incidence of early-onset colorectal cancer increased 35% for those living in rural areas
  - Cancer Mortality is 12/3% higher in US Counties where poverty is persistent compared to where poverty was no persistent
  - Women with no health insurance have double the likelihood of diagnosis of late stage breast cancer who are privately insured
- **Fast Facts on New Drug Approvals**
  - In 2020-2021, the US Food and Drug Administration (FDA) approved 16 new anticancer therapeutics and expanded the use of 11 previously approved anticancer therapeutics for treating new types of cancer.
  - In May 2021, the FDA approved the first molecularly targeted therapeutic against the protein KRAS, which has long been considered an undruggable target, for the treatment of certain patients with lung cancer. The agent, sotorasib (Lumakras), targets an altered form of the protein, KRAS G123C and is a new treatment option for NSCLC.
  - In March 2021, the FDA approved the first CAR T-cell therapy for treatment of patients with multiple myeloma.
  - In April 2021, the FDA approved a new immune checkpoint inhibitor, dostarlimab-gxly (Jemperli) for treatment of patients with endometrial cancer

4

# 2022 Incidence & Mortality Estimates

5



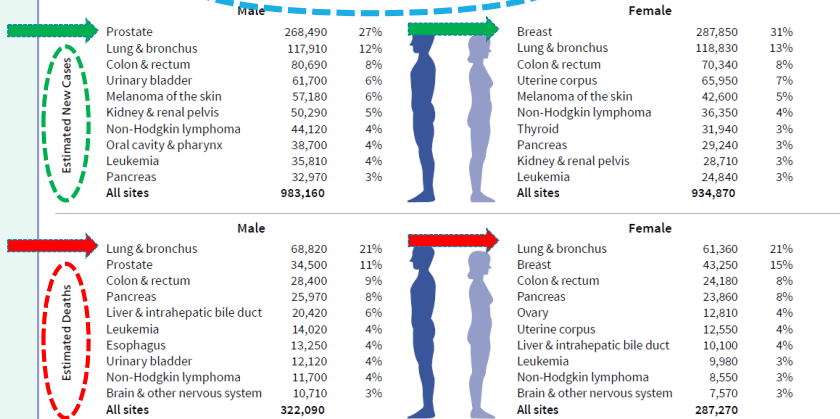
2022 Cancer Facts and Figures – American Cancer Society

5

# 2022 Incidence & Mortality Estimates

6

Figure 3. Leading Sites of New Cancer Cases and Deaths – 2022 Estimates



Estimates are rounded to the nearest 10, and cases exclude basal cell and squamous cell skin cancers and in situ carcinoma except urinary bladder. Estimates do not include Puerto Rico or other US territories. Ranking is based on modeled projections and may differ from the most recent observed data.

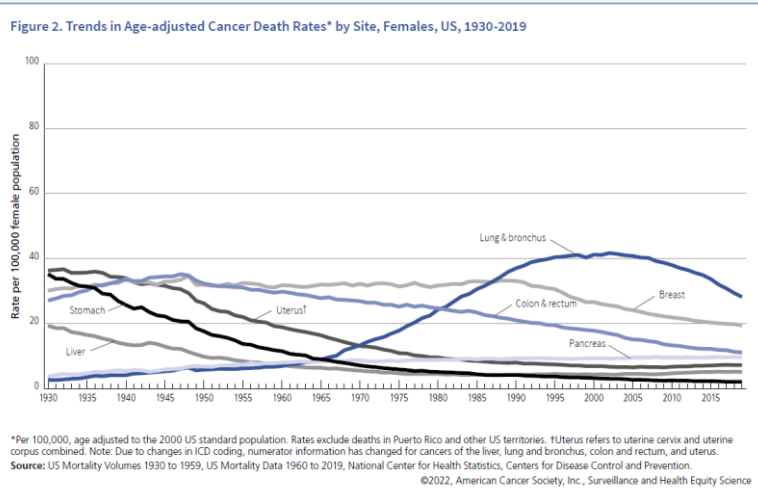
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# Trends in Death Rates – Female 1930-2019

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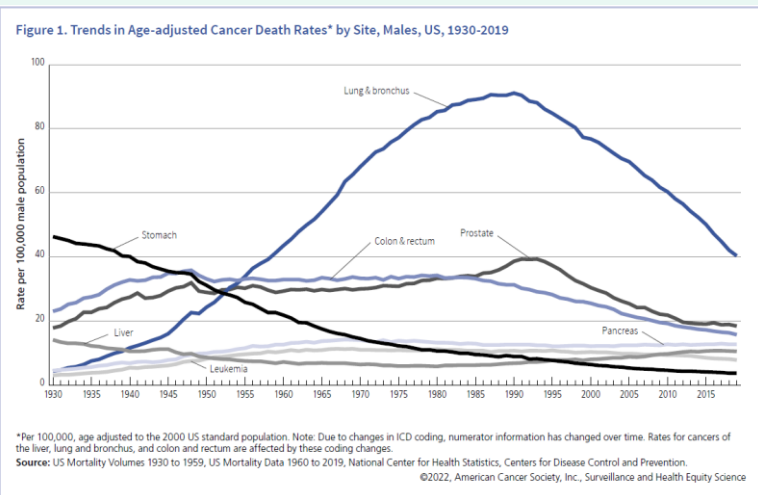


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# Trends in Death Rates – Male 1930-2019

8



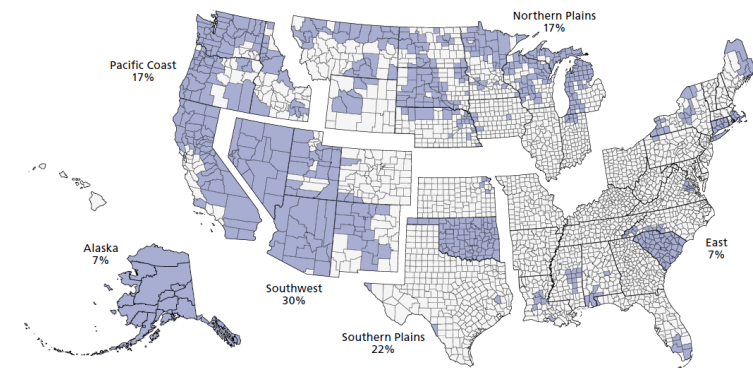
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# American Indian and Alaska Native Populations

9

Figure S1. PCRDA Counties and the Distribution of American Indian and Alaska Native Persons by Region



PCRDA: Purchased/Referred Care Delivery Area. Percentages represent the proportion of the non-Hispanic American Indian/Alaska Native PCRDA population that lives in each region (shown in blue).  
Source: US Census Bureau, 2019.

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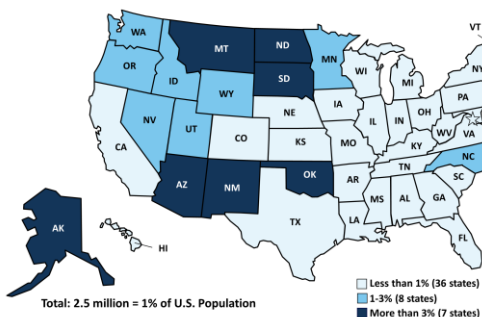
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# American Indian and Alaska Native Populations

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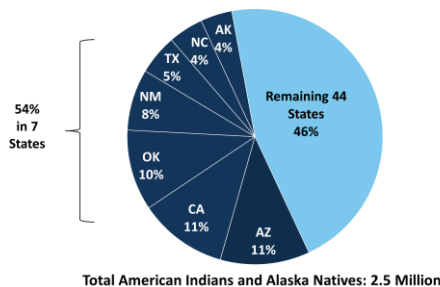
American Indians and Alaska Natives as a Share of the Total Population, by State, 2009-2011



American Indian and Alaska Native includes people of Hispanic origin.  
SOURCE: KCMU analysis of 2009 - 2011 ACS.



Distribution of American Indians and Alaska Natives Across States, 2009-2011



American Indian and Alaska Native includes people of Hispanic origin. Totals do not sum due to rounding.  
SOURCE: KCMU analysis of 2009-2011 ACS.

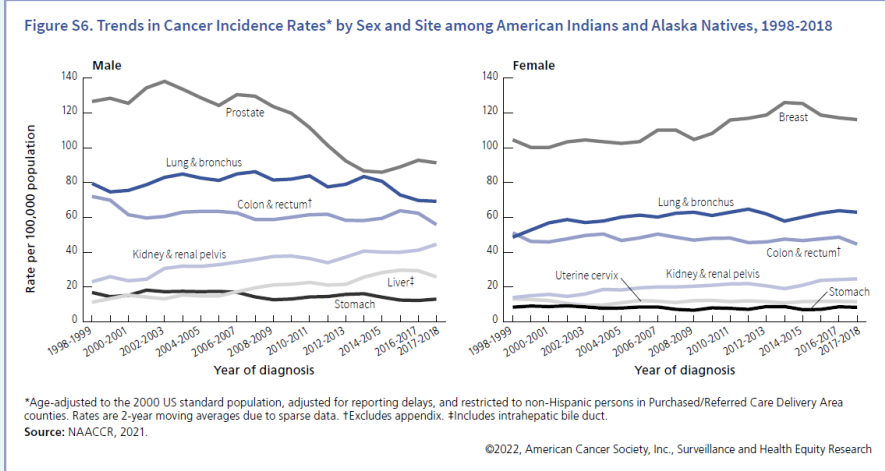


Kaiser Family Foundation

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# 2022 Incidence Rates Among AIAN Populations

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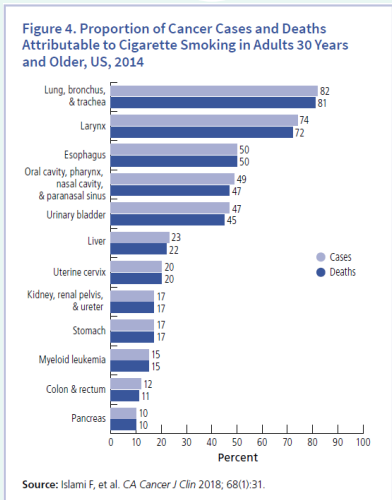


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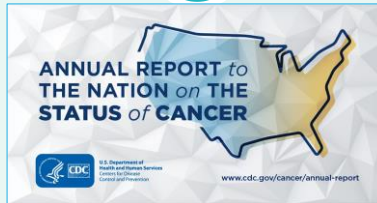


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# 2021 Annual Report to the Nation on the Status of Cancer

13



OXFORD

JNCI Natl Cancer Inst (2021) 113(12): djab131

doi: 10.1093/jnci/djab131  
First published online July 8, 2021  
Article

Annual Report to the Nation on the Status of Cancer, Part 1: National Cancer Statistics

Farhad Islami <sup>1</sup>, MD, PhD, <sup>1\*</sup> Elizabeth M. Ward <sup>2</sup>, PhD, <sup>2</sup> Hyuna Sung <sup>3</sup>, PhD, <sup>3</sup> Kathleen A. Cronin <sup>4</sup>, PhD, <sup>3</sup> Florence K. L. Tangka, PhD, <sup>4</sup> Recinda L. Sherman <sup>5</sup>, PhD, <sup>7</sup> Jingxuan Zhao <sup>6</sup>, MPH, <sup>1</sup> Robert N. Anderson, PhD, <sup>5</sup> S. Jane Henley <sup>6</sup>, MSPH, <sup>4</sup> K. Robin Yabroff <sup>6</sup>, PhD, <sup>1</sup> Ahmedin Jemal <sup>6</sup>, DVM, PhD, <sup>1</sup> Vicki B. Benard, PhD <sup>4</sup>

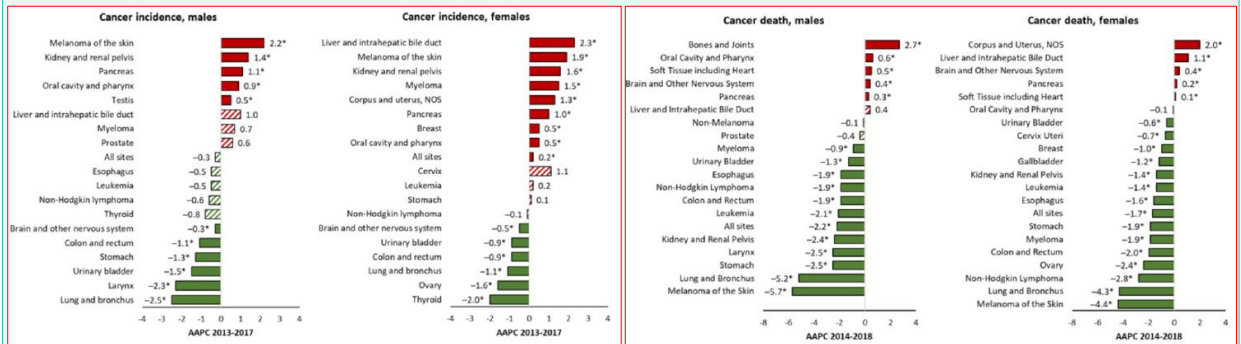


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# 2021 Annual Report to the Nation on the Status of Cancer

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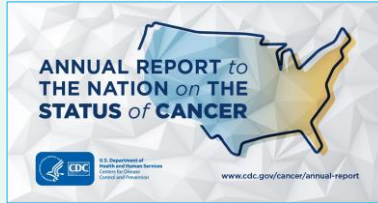
Average annual percent change (AAPC) in age-standardized, delay-adjusted incidence rates for 2013-2017



14

# 2021 Annual Report to the Nation on the Status of Cancer

15



JNCI Natl Cancer Inst (2021) 113(12): djab192  
 doi: 10.1093/jnci/djab192  
 First published online October 26, 2021  
 Article



## Annual Report to the Nation on the Status of Cancer, Part 2: Patient Economic Burden Associated With Cancer Care

K. Robin Yabroff, PhD <sup>1,\*</sup>, Angela Mariotto, PhD <sup>2</sup>, Florence Tangka, PhD <sup>3</sup>, Jingxuan Zhao, MPH <sup>1</sup>, Farhad Islami, MD, PhD <sup>1</sup>, Hyuna Sung, PhD <sup>1</sup>, Recinda L. Sherman, PhD <sup>4</sup>, S. Jane Henley, MSPH <sup>3</sup>, Ahmedin Jemal, DVM, PhD <sup>4</sup>, Elizabeth M. Ward, PhD <sup>4</sup>



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# Cancer Trends Progress Report – 20<sup>th</sup> Anniversary

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**20<sup>th</sup> Anniversary**

## Cancer Trends Progress Report

progressreport.cancer.gov

### Online Summary of Trends in U.S. Cancer Control Measures

The Cancer Trends Progress Report summarizes our nation's progress against cancer in relation to Healthy People targets set forth by the Department of Health and Human Services. The online report, intended for policy makers, researchers, and public health professionals, includes key measures of progress along the cancer control continuum and uses national trend data to illustrate where improvements have been made.

**Report Features:**

- Downloadable graphs and Excel data
- Ability to generate printer-friendly custom reports
- Sharing options via email and social media
- Links to related cancers and statistics

The Cancer Trends Progress Report, continually updated since its first issue in 2001, summarizes our nation's advances against cancer in relation to Healthy People targets set forth by the Department of Health and Human Services. The report, intended for policy makers, researchers, and public health professionals, includes key measures of progress along the cancer control continuum and uses national trend data to illustrate where improvements have been made and where attention is demanded. New measures this year include Sleep, Melanoma of the Skin Treatment, Outdoor Tanning, and Evidence-based Smoking Cessation Aids.

	<p><b>Prevention</b></p> <p>Focuses on factors that have been observed to affect a person's risk of getting cancer: behaviors, selected environmental exposures, policies, and regulations.</p> <ul style="list-style-type: none"> <li>Behavioral Factors</li> <li>Tobacco Policy/Regulatory Factors</li> <li>HPV Vaccination</li> <li>Environmental Factors</li> <li>Genetic Testing</li> </ul>
	<p><b>Early Detection</b></p> <p>Describes trends in the use of mammography, Pap tests, HPV tests, fecal occult blood tests, colonoscopies, CT scans, and PSA blood tests.</p> <ul style="list-style-type: none"> <li>Breast Cancer</li> <li>Cervical Cancer</li> <li>Colorectal Cancer</li> <li>Lung Cancer</li> <li>Prostate Cancer</li> </ul>
	<p><b>Diagnosis</b></p> <p>Provides rates of new cases by cancer site and by race/ethnicity, as well as stage at diagnosis.</p> <ul style="list-style-type: none"> <li>Incidence</li> <li>Stage at Diagnosis</li> </ul>
	<p><b>Treatment</b></p> <p>Summarizes trends in quality of care, clinical trials, patterns of care, emerging treatments, and associated outcomes.</p> <ul style="list-style-type: none"> <li>Bladder Cancer</li> <li>Breast Cancer</li> <li>Kidney Cancer</li> <li>Colorectal Cancer</li> <li>Lung Cancer</li> <li>Melanoma of the Skin</li> <li>Ovarian Cancer</li> <li>Prostate Cancer</li> </ul>
	<p><b>Life After Diagnosis</b></p> <p>Explores 5-year survival rates for some of the leading cancers as well as the economic impact of cancer treatment costs.</p> <ul style="list-style-type: none"> <li>Financial Burden of Care</li> <li>Cancer Survivors and Smoking</li> <li>Cancer Survivors and Weight</li> <li>Cancer Survivors and Physical Activity</li> </ul>
	<p><b>End of Life</b></p> <p>Provides data on cancer mortality by common cancer sites, along with years of life lost due to cancer and other major causes of death.</p> <ul style="list-style-type: none"> <li>Mortality</li> <li>Years of Life Lost</li> </ul>

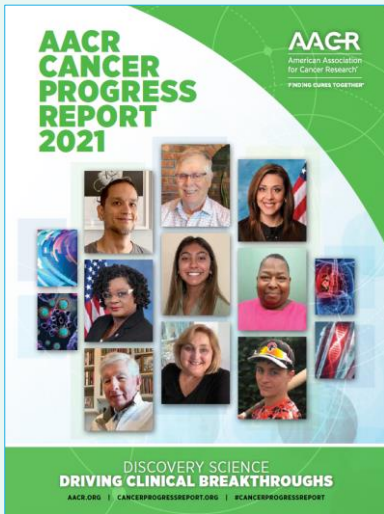
Cancer Trends Progress Report, National Cancer Institute, NIH, HHS, Bethesda, February 2022, <https://progressreport.cancer.gov>

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# AACR Cancer Progress Report 2021

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# AACR Cancer Progress Report 2021

## A Few Interesting Highlights

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- Landmark Discoveries Fueling Advances in Lung Cancer Diagnosis and Treatment
- Detecting Early Signs of Multiple Types of Cancer from a Single Minimally Invasive Screening Test
- Advances in Treatment with Surgery
  - Non-invasive Bone Tumor Procedures
  - Using Artificial Intelligence for Precision in Surgical Oncology
- Improvements in Radiation-Based Approaches for Cancer Care
  - Imaging Prostate Cancer More Clearly
  - Detecting Neuroendocrine Tumors with High Accuracy
- Advances in Treatment with Cytotoxic Chemotherapy
  - Reducing the Risk of Blood Cancer Recurrence
  - Effectively Delivering Cytotoxic Drugs to Kill Multiple Myeloma Cells
- Advances in Treatment with Molecularly Targeted Therapy
  - New Breakthrough in Treating Lung Cancer
  - Targeting Protein Kinases for Treatment of Solid Tumors
- Advances in Cancer Immunotherapy
  - Engineering Immune Cells to Eliminate Cancer
  - Unleashing the Body's Defense System Against Cancer
- Artificial Intelligence: Shaping the Future of Cancer Science and Medicine
- Supporting a Vibrant and Diverse Cancer Research Workforce
- Addressing Cancer Health Disparities

**BETWEEN AUGUST 1, 2020 AND JULY 31, 2021, THE FDA APPROVED:**

- 16 new anticancer therapeutics, which are now benefiting patients with various types of cancer
- 11 previously approved anticancer therapeutics for treating new types of cancer
- 3 new diagnostic imaging agents
- 2 new surgery guiding devices
- 1 new artificial intelligence-driven endoscopy device
- 2 new multipanel NGS liquid biopsy companion diagnostic tests

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# AACR Cancer Progress Report 2021

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## 50TH ANNIVERSARY OF THE NATIONAL CANCER ACT OF 1971



President Nixon signed the National Cancer Act at a ceremony in the East Room on December 23, 1971.

**"I hope in the years ahead we will look back on this action today as the most significant action taken during my Administration."**  
— Richard M. Nixon

The year 2021 marks the 50th anniversary of the National Cancer Act of 1971, a groundbreaking legislation that launched a national commitment to ending preventable cancer by providing the National Cancer Institute (NCI) with broad authority and innovative mechanisms to drive our understanding of the devastating challenge of cancer. Years of advocacy by patients and survivors of cancer, researchers, physicians, and others led to the enactment and eventual passage of the bill, which was signed into law by President Richard Nixon on December 23, 1971.

One of the most consequential provisions of the National Cancer Act was the establishment of the NCI Cancer Program to investigate and support innovative science across the spectrum of cancer biology, from cancer prevention, diagnosis, and treatment. The legislation initially provided the funding to establish 11 cancer research centers and local cancer control programs. Today, there are 73 NCI-designated cancer centers across the nation and the University of Colorado has joined on December 23, 2021.

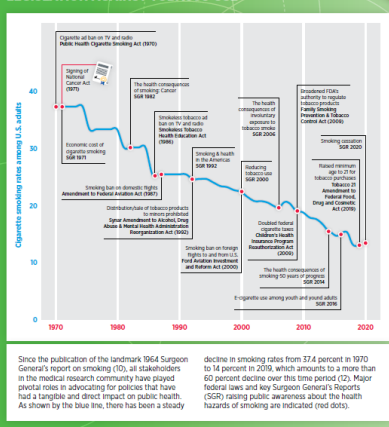
In the 50 years since the Act was signed into law, NCI-designated cancer centers have been at the forefront of new discoveries in basic, clinical, and translational science that have revolutionized the way we understand and treat cancer. These centers also serve as the point of care for patients in their communities and beyond, providing access to the latest treatments currently available as well as exploring new therapies through clinical trials. Many of these researchers also provide community-based cancer screening and advanced public education in collaboration with local partners. Additionally, NCI-designated cancer centers lead the way in training the next generation of cancer scientists through a variety of educational programs, fellowships, and internships.



**"The National Cancer Act of 1971 was a watershed moment in our nation's fight against this terrible scourge of disease. Advances and promises revealed through cancer research that have led to 100 years of progress in preventing, treating, and curing cancer. Commemorating this anniversary is a reaffirmation of the original intention of the National Cancer Act: to bring to you a cure or to prevent cancer as we know it."**  
— Richard M. Nixon, President

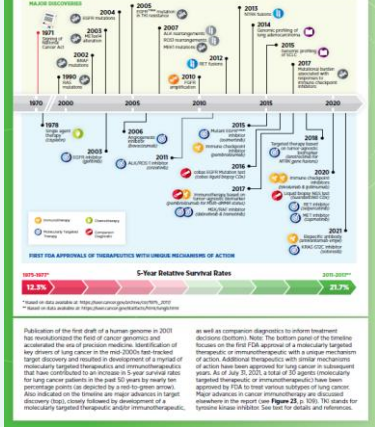
1 | AACR Cancer Progress Report 2021

**FIGURE 3  
REFLECTING ON FIVE DECADES OF POLICIES AND LEGISLATION AGAINST TOBACCO USE**



Since the publication of the landmark 1964 Surgeon General's report on smoking (20), as stakeholders in the medical research community have played pivotal roles in advocating for policies that have had a tangible and direct impact on public health. As shown by the blue line, there has been a steady decline in smoking rates from 37.4 percent in 1970 to 14 percent in 2020, which amounts to a more than 60 percent decline over this time period (20). Major federal laws and key Surgeon General's Reports (SSR) raising public awareness about the health hazards of smoking are indicated (red dots).

**FIGURE 4  
50 YEARS OF PROGRESS AGAINST LUNG CANCER**



Publication of the first draft of a human genome in 2001 has revolutionized the field of cancer genomics and accelerated the use of precision medicine. Identification of key driver mutations in the early 2000s has revealed target discovery and resulted in development of a myriad of molecularly targeted therapeutic and immunotherapeutic agents that have contributed to an increase in 5-year survival rates for lung cancer patients in the past 10 years (26). More also indicates on the timeline are major advances in target discovery that have led to development of a variety of molecularly targeted therapies and immunotherapeutics.

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# AACR Cancer Progress Report 2021 Other Interesting Highlights

20

## A SNAPSHOT OF A YEAR IN PROGRESS

**1991**

**31% Reduction in overall cancer death rate**

**BETWEEN AUGUST 1, 2020 AND JULY 31, 2021, THE FDA APPROVED:**

- 11 new anticancer therapeutics, which are now treating patients with various types of cancer
- 10 previously approved anticancer therapeutics for treating new types of cancer
- 5 new diagnostic imaging agents
- 2 new surgery guiding devices
- 1 new artificial intelligence-driven antibody device
- 2 new molecular NGS liquid biopsy companion diagnostic tests

**RESEARCH CONTINUES TO ADVANCE IMMUNOTHERAPY, LEADING TO:**

- The first approval of a CAR T cell therapy for the treatment of patients with multiple myeloma, such as **David's Blinatumomab** (Davi-10) (Nov 18)
- A new immune checkpoint inhibitor for treating patients with metastatic colorectal cancer who had received treatment in the past, such as **Pulvisine** (Nov 18)
- The first approval of immune checkpoint inhibitor for treating patients with metastatic cancer, such as **Samal** (Nov 18)

**RESEARCH CONTINUES TO POWER PRECISION MEDICINE, LEADING TO:**

- The first therapeutic to target KRAS, which is providing new options for patients with non-small cell lung cancer, such as **Sotorasib** (Nov 18)
- The first antibody-drug conjugate for patients with HER2-positive gastric cancer, such as **Trastuzumab** (Nov 18)
- The first use of immune therapy for treating patients with advanced gastric cancer (Nov 18)

## SOURCES OF GENETIC MUTATIONS

Cancer initiation and progression are predominantly caused by the accumulation of changes, or mutations, in the genetic material of a cell over time. The primary sources of genetic mutations are as follows:

- Hereditary mutations:** Nearly 10 percent of cancer cases are linked to inherited genetic mutations (see **Table 2**, p. 33), which are mutations that are present in each cell of the body from birth (114-117).
- Most mutations, however, are acquired during a person's lifetime.** Some occur during cell multiplication, and the number of times a cell multiplies increases the chance that it will acquire a mutation.
- Some occur because of persistent exposure to substances that damage genetic material, such as carcinogens in tobacco smoke and ultraviolet radiation from the sun** (see **Figure 7**, p. 37).
- Other mutations occur because of chronic inflammation caused by medical conditions such as Crohn's disease** (158, 159).

These factors come together to determine the chance that an individual cell has of acquiring mutations over time, which in turn determines the overall risk that a person will develop cancer. It is important to note that not all mutations lead to cancer.

## UNRAVELING THE COMPLEXITIES OF CANCER GENOMICS

Recent work from an international team of scientists has provided critical insights into cancer genomics with potential implications for early detection, intervention, and treatment. The researchers analyzed the whole genomes from >2600 tumor samples spanning 38 different types of cancer (440). Among the most important findings were the following:

- Most tumors contain at least one identifiable mutation in their genomes that appears to drive tumor growth, and on an average each cancer genome was found to contain between four and five such "driver" mutations (42).
- Unique patterns of mutations referred to as "mutational signatures" are often associated with processes or events that lead to cancer development, such as defective DNA repair mechanisms or exposure to cancer risk factors such as environmental carcinogens, tobacco in tobacco smoke, or ultraviolet radiation (42).
- By analyzing the vast array of genetic changes, the researchers were able to determine the chronology of cancer-causing mutations. They found that many mutations can occur years, if not decades, prior to a cancer diagnosis (42).

Results from three recent studies have provided a deeper understanding of the inherited genetic mutations that predispose women to breast cancer. The prevalence of such mutations in the general population, and the earliest cellular and molecular changes in presumably healthy breast tissue, prior to tumor development, among individuals with inherited mutations (44-46). These data are critical for the development of early diagnostic testing or cancer prevention interventions for women who are susceptible to breast cancer development.

In a recent paper, researchers outlined new details regarding the contribution of inherited genetic mutations in the development of childhood cancers (147). These data can be used not only to select the most appropriate treatment for certain patients, but also to tailor prevention and screening for patients and/or their family members who harbor similar mutations and even for future family planning purposes.

Data from a recent publication provide significant new insight into the development of blood cancer (148). Notably, the study reported that certain mutations associated with leukemias and other blood cancers are also detected, albeit at low levels, among seemingly healthy individuals, showcasing a potential for pre-cancer surveillance and/or interception.

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# AACR Cancer Progress Report 2021

## More Interesting Highlights

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### NEWLY FDA-APPROVED ANTICANCER THERAPEUTICS: AUGUST 1, 2020-JULY 31, 2021

Approved Indication	Generic Name	Trade name	Formulation
<b>Angiogenesis Inhibitors</b>			
Certain type of kidney cancer	tesezarit	Fotivda	
<b>Cell-signaling Inhibitors</b>			
Certain type of lung cancer	amivantamab-vmyer	rybrevant	
Certain type of non-Hodgkin lymphoma*	crovalimab	Xalcan	
Certain types of lung and thyroid cancers	prasopritinib	Corelio	
Certain type of lung cancer	lapatinib	Tepnelco	
Certain types of non-Hodgkin lymphoma	umbralisib	Ukoniq	
Certain type of lung cancer	rocicicab	Lumakras	
Certain type of leukemia*	acipristinib	Avykat	
bile duct cancer	infigratinib	Truseltiq	
<b>Cell Cycle/Cell-signaling Modifying Agents</b>			
Multiple myeloma	bezarotamab-mandotin-bmr	Blenrep	
<b>DNA-damaging Agents</b>			
Certain type of gastrointestinal cancers*	tam-trastuzumab deruxtecan-nxk	Eshertty	
Certain type of bladder cancer*	tafasutamide-gemtacin-hcy	Trodelvy	
Certain type of non-Hodgkin lymphoma	loncastatamab besimec-tyqr	Zynovata	
Multiple myeloma	meqazineb rutanerside	Pegapato	
Certain type of leukemia*	azacitidine	Onuzyg	
<b>Hormones, Antihormones</b>			
Certain type of prostate cancer	relixigala	Orgovyx	
<b>Immunotherapeutics</b>			
Certain types of skin and lung cancers*	camplimab-rwv1	Ultigo	
Certain type of non-Hodgkin lymphoma	tocotrigene malatecoel	Breaznet	
Certain type of non-Hodgkin lymphoma*	secotrigene cilostazol	Yescarta	
Neuroblastoma	spisiranib and rivocicab	Yervoy and Opdivo	
Neuroblastoma	nasitanib-jgqg	Danavex	
Multiple myeloma	idecabtagene viclest	Abecma	
Certain type of endometrial cancer	docosanol-glyr	Jampetris	
Gastric and gastroesophageal junction cancer*	rexcicab	Opdivo	
Certain type of breast cancer*	mipgicabimab-cmb	Mergyzta	
Certain types of breast, gastric, and gastroesophageal junction cancer*	peramivir-mab	Meruvia	
<b>Imaging Agents</b>			
Prostate cancer	gallium 68 PSMA-11	Ga 68 PSMA-11	
Prostate cancer	pituitrastat F-18	Pivalfy	
Certain type of neuroendocrine tumor	copper Cu 64 doxotate	Dotectnet	
<b>Companion Diagnostic Tests</b>			
Certain type of lung cancer	N/A	Guardant360 CDx	
Certain types of breast, lung, ovarian, and prostate cancers	N/A	FoundationOne Liquid CDx	
<b>Surgical Guiding Devices</b>			
Crossed osteoma in the extremities	N/A	Sonatype MS-HFU system	
Artificial intelligence-guided assessment for liver cancer	N/A	Hepatica	

\*New cancer type approved 2020-2021  
†Requires surveillance regimen



#### Single base changes

- Deletion, insertion, or substitution of a single base can result in new proteins, altered versions of normal proteins, or loss of protein function, which can lead to cancer.



#### Extra copies of genes (gene amplification)

- Higher quantities of certain proteins can result in enhanced cell survival and growth, leading to cancer.



#### Deletions

- Loss of DNA can result in loss of genes necessary to regulate the processes that control normal cell growth, division, and life span, leading to cancer development.



#### Structural variations

- Exchange of DNA between chromosomes can alter multiple genes at once. It can sometimes lead to the fusion of two separate genes, generating entirely new proteins that can drive the development of cancer.

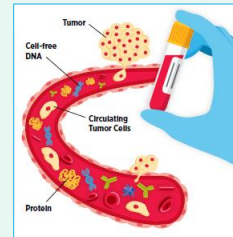
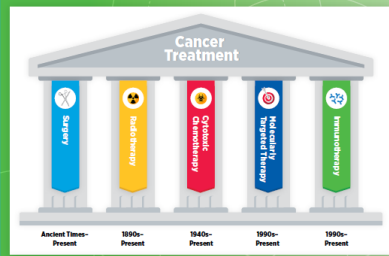


#### Mutations that alter the epigenome

- Several proteins read, write, or erase epigenetic marks on DNA or the histones around which DNA is packaged. Mutations in the genes that produce these proteins can lead to cancer by altering the coordinated activation or silencing of genes needed to control cell growth and division processes.



### THE PILLARS OF CANCER TREATMENT



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# NCCN Annual Report 2021

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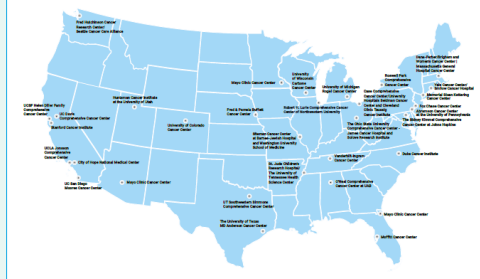


Quality  
Effective  
Equitable  
Accessible

NCCN 2021 Annual Report

### NCCN Member Institutions

The National Comprehensive Cancer Network® (NCCN) is a not-for-profit alliance of 31 leading cancer centers devoted to patient care, research, and education. To learn more, visit [NCCN.org/cancercenters](https://www.nccn.org/cancercenters)



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# NCCN Annual Report 2021

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Quality Care through NCCN Guidelines

82 Total NCCN Guidelines

>40,000 Hours NCCN Guidelines Panels contributed

3 New NCCN Guidelines published in 2021

- Histologic Neoplasms
- Malignant Peripheral Mesothelioma
- Wilms Tumor (Nephroblastoma)

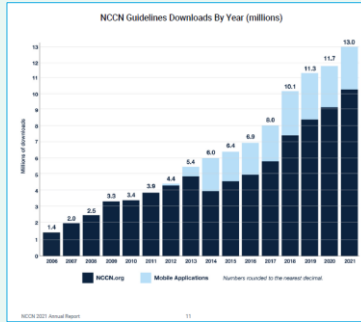
>1.5 million Registered users of NCCN Guidelines

60 NCCN Guidelines Panels

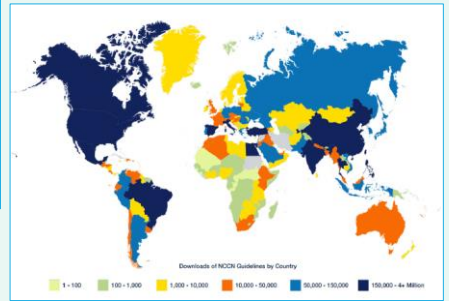
>4.2 million Unique visitors to NCCN.org

>1,700 NCCN Guidelines Panel Members

NCCN Guidelines Downloads By Year (millions)



Downloads of NCCN Guidelines by Country in 2021



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# ASCO Report on Progress Against Cancer 2021

<http://ascopubs.org/doi/full/10.1200/JCO.20.03420>

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Volume 39, Issue 10 April 1, 2021

**Journal of Clinical Oncology**<sup>®</sup>

An American Society of Clinical Oncology Journal

ASCO special articles

Featured Content  
ASCO Special Article  
Clinical Cancer Advances 2021: ASCO's Report on Progress Against Cancer  
S.M. Smith et al.

ASCO  
AMERICAN SOCIETY OF CLINICAL ONCOLOGY

## Clinical Cancer Advances 2021: ASCO's Report on Progress Against Cancer

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### Advance of the Year: Molecular Profiling Drives Progress in GI Cancers

Surgery, radiotherapy, and chemotherapy have been the mainstay of treatment for GI cancer but have limited effect and can take a heavy toll on quality of life. The development of more effective therapies for GI cancer has lagged. Molecular profiling has helped change the outlook for patients with GI cancer by identifying the molecular and genetic signatures that allow oncologists to deliver treatments that are highly specific to a tumor. For these reasons, ASCO has identified molecular profiling driving progress in GI cancer as the 2021 Advance of the Year. This selection recognizes the treatment advances made possible by molecular testing for patients with GI cancers.

GI cancer includes cancer of the esophagus, stomach, small intestine, colon, rectum, and anus. The incidence of GI cancer is rising, while the survival rate is low. Molecular profiling, the use of genetic and molecular data to identify the specific genetic changes in a tumor, is now driving progress in the treatment of GI cancer.

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# ASCO Report on Progress Against Cancer 2021

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New therapies or tests	
October 2020	
NGS-based FoundationOne CDx test	A companion diagnostic to identify fusions in neurotrophic receptor tyrosine kinase (NTRK) genes, <i>NTRK1</i> , <i>NTRK2</i> , and <i>NTRK3</i> in DNA isolated from tumor tissue specimens from patients with symptoms eligible for treatment with lapatinib
September 2020	
Prasitinib (GAWRETO)	For adult patients with metastatic RET fusion-positive non-small-cell lung cancer (NSCLC) as detected by an FDA-approved test
Azacitidine tablets (ONUREG)	For continued treatment of patients with acute myeloid leukemia who achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy and are not able to complete intensive curative therapy
August 2020	
FoundationOne Liquid CDx test	A companion diagnostic to identify mutations in <i>BRCA1</i> and <i>BRCA2</i> genes in cell-free DNA isolated from plasma specimens from patients with metastatic castration-resistant prostate cancer (mCRPC) eligible for treatment with rucaparib (RUBRACA)
Belarotimab mafodotin-dimf (BLENREP)	For adult patients with relapsed or refractory multiple myeloma who have received at least 4 prior therapies, including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent
July 2020	
Breucabtagene autixesol (TECARTUS)	A CD19-directed genetically modified autologous T cell immunotherapy for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL)
June 2020	
Tazemetostat (TAZVERK)	An EZH2 inhibitor for adult patients with relapsed or refractory (RR) follicular lymphoma (FL) whose tumors are positive for an EZH2 mutation as detected by an FDA-approved test and who have received at least 2 prior systemic therapies, and for adult patients with R/R FL who have no satisfactory alternative treatment options
Lurbinectedin (ZEP-ZELCA)	For adult patients with metastatic small-cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy
May 2020	
Brigatinib (ALUNBRIG)	For adult patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small-cell lung cancer (NSCLC) as detected by an FDA-approved test
Ripretinib (QINLOCK)	For adult patients with advanced GI stromal tumor (GIST) who have received prior treatment with 3 or more kinase inhibitors, including imatinib
Capmatinib (TABRECTA)	For adult patients with metastatic non-small-cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test
Daratumumab and hyaluronidase-ihj (DARZALEX FASPRO)	For adult patients with newly diagnosed or relapsed or refractory multiple myeloma. This new product allows for subcutaneous dosing of daratumumab
April 2020	
Sacituzumab govitecan-hzy (TRODELVY)	For adult patients with metastatic triple-negative breast cancer who received at least two prior therapies for metastatic disease

Pemigatinib (PEMAZYRE)	For the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement, as detected by an FDA-approved test
Selumetinib (KOSELUGO)	For pediatric patients, 2 years of age and older, with neurofibromatosis type 1 (NF1) who have comorbid, inoperable plexiform neurofibromas (PN)
Midostatin (LUMIFYO)	For adult patients with low-grade upper tract urothelial cancer (LGUTUC)
January 2020	
Tazemetostat (TAZVERK)	For adults and pediatric patients age 16 years and older with metastatic or locally advanced epithelioid sarcoma not eligible for complete resection
Asaprisin (AVAKIT)	For adults with unresectable or metastatic GI stromal tumor (GIST) harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including LB42V mutations
December 2019	
Fam-trastuzumab deruxetan-nikei (ENHERLIO)	For patients with unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting
Enfortumab vedotin-ehv (PADCEV)	For adult patients with locally advanced or metastatic urothelial cancer who have previously received a programmed death receptor 1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor, and a platinum-containing chemotherapy in the neoadjuvant or adjuvant, locally advanced, or metastatic setting
November 2019	
Givosiran (GIVLAARI)	For adults with acute hepatic porphyria (AHP)
New Uses	
October 2020	
Venetoclax (VENCLIXTA)	In combination with azacitidine, decitabine, or low-dose cytarabine (LDAC) for newly diagnosed acute myeloid leukemia (AML) in adults 75 years of age or older, or who have comorbidities precluding intensive induction chemotherapy
Nivolumab (OPDIVO) plus ipilimumab (YERVOY)	First-line treatment for adult patients with unresectable malignant pleural mesothelioma
August 2020	
Carfilzomib (KYPROLIS) and daratumumab (DARZALEX)	In combination with dexamethasone for adult patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy
July 2020	
Teclistamab-oxi (MONLUVI)	A CD19-directed cytolytic antibody, indicated in combination with lenalidomide for adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low-grade lymphoma, and who are not eligible for autologous stem-cell transplant
Atezolizumab (TECENTRIQ)	In combination with carboplatin and vinorelbine for patients with BRCA1/2 mutation-positive unresectable or metastatic melanoma
June 2020	
Pembrolizumab (KEYTRUDA)	For the first-line treatment of patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer
Pertuzumab, trastuzumab, and hyaluronidase-xyz (PHERESO)	A new fixed-dose combination for subcutaneous injection for treatment of patients with HER2-positive early breast cancer
Pembrolizumab (KEYTRUDA)	For patients with recurrent or metastatic cutaneous squamous cell carcinoma (cSCC) that is not curable by surgery or radiation

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# ASCO Report on Progress Against Cancer 2021

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Pembrolizumab (KEYTRUDA)	For the treatment of adult and pediatric patients with unresectable or metastatic tumor mutational burden-high (TMB-H) ( $\geq 10$ mutations/megabase [mut/Mb]) solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options
Nivolumab (OPDIVO)	For patients with unresectable advanced, recurrent, or metastatic esophageal squamous cell carcinoma (ESCC) after prior fluoropyrimidine- and platinum-based chemotherapy
Avelumab (BAVENDO)	For maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) that has not progressed with first-line platinum-containing chemotherapy
May 2020	
Ramucicab (CYRAMZA)	In combination with irinotecan for first-line treatment of metastatic non-small-cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) mutations
Atezolizumab in combination with bevacizumab (TECENTRIQ and AVASTIN)	For patients with unresectable or metastatic hepatocellular carcinoma who have not received prior systemic therapy
Nivolumab (OPDIVO) in combination with ipilimumab (YERVOY) and 2 cycles of platinum-doublet chemotherapy	First-line treatment for patients with metastatic or recurrent non-small-cell lung cancer (NSCLC), with no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations
Nivolumab (OPDIVO) in combination with ipilimumab (YERVOY)	First-line treatment for patients with metastatic non-small-cell lung cancer whose tumors express PD-L1 ( $\geq 1\%$ ), as determined by an FDA-approved test, with no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations
Pomalidomide (POMALYST)	Expanded the indication to include treating adult patients with AIDS-related Kaposi sarcoma after failure of highly active antiretroviral therapy and Kaposi sarcoma in adult patients who are HIV-negative
Olaparib (LYNPARZA)	Expanded the indication to include its combination with bevacizumab for first-line maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal carcinoma who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency positive status defined by either a deleterious or suspected deleterious BRCA mutation, and/or germline instability
Olaparib (LYNPARZA)	For adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-related metastatic castration-resistant prostate cancer (mCRPC), who have progressed following prior treatment with enzalutamide or abiraterone
Atezolizumab (TECENTRIQ)	For the first-line treatment of adult patients with metastatic non-small-cell lung cancer (NSCLC) whose tumors have high PD-L1 expression (PD-L1 stained $\geq 50\%$ of tumor cells [TC $\geq 50\%$ ] or PD-L1 stained tumor-infiltrating immune cells [IC covering $\geq 10\%$ of the tumor area [IC $\geq 10\%$ ]), with no EGFR or ALK genomic tumor aberrations
Rucaparib (RUBRACA)	For patients with deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy
Sepraparib (RELEVMO)	For the following indications: adult patients with metastatic RET fusion-positive non-small-cell lung cancer (NSCLC); adult and pediatric patients $\geq 12$ years of age with advanced or metastatic RET mutant medullary thyroid cancer (MTC) who require systemic therapy; adult and pediatric patients $\geq 12$ years of age with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate)

April 2020	
Ninaparib (ZELJULA)	For the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal carcinoma who are in a complete or partial response to first-line platinum-based chemotherapy
Pembrolizumab (KEYTRUDA)	New dosing regimen of 400 mg every 6 weeks for pembrolizumab (KEYTRUDA) across all currently approved adult indications in addition to the current 200 mg every 3 weeks dosing regimen
Tucatinib (TUKYSA) combination with trastuzumab and capecitabine	For adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting
Encorafenib (BRAFTOVI) in combination with cetuximab	For the treatment of adult patients with metastatic colorectal cancer (CRC) with a BRAF V600E mutation, detected by an FDA-approved test, after prior therapy
March 2020	
Darunavir (MIRVIZI) in combination with etoposide and either carboplatin or cisplatin	First-line treatment of patients with extensive-stage small-cell lung cancer
Nivolumab and ipilimumab (OPDIVO and YERVOY)	For patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib
Isatuximab-ihf (SARCLISA) in combination with pomalidomide and dexamethasone	For adult patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor
February 2020	
Neratinib (NERLYN) in combination with capecitabine	For adult patients with advanced or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting
January 2020	
Pembrolizumab (KEYTRUDA)	For the treatment of patients with Bacillus Calmette-Guérin (BCG)-unresponsive, high-risk, nonmuscle-invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) who are treated with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy
December 2019	
Olaparib (LYNPARZA)	For the maintenance treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) metastatic pancreatic adenocarcinoma, as detected by an FDA-approved test, whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen
Atezolizumab (TECENTRIQ) in combination with paclitaxel protein-bound and carboplatin	For the first-line treatment of adult patients with metastatic non-small-cell lung cancer (NSCLC) with no EGFR or ALK genomic tumor aberrations
Enzalutamide (XANDRI)	For patients with metastatic castration-sensitive prostate cancer (mCSPC)
October 2019	
Ninaparib (ZELJULA)	For patients with advanced ovarian, fallopian tube, or primary peritoneal cancer treated with three or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency (HRD)-positive status. HRD is defined by either a deleterious or suspected deleterious BRCA mutation, or germline instability in patients with disease progression greater than 6 months after response to the last platinum-based chemotherapy

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## FDA New Drug Therapy Approvals in 2021

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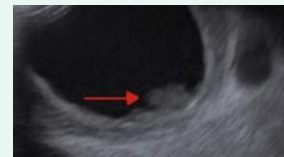
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## New Developments in Cancer Incidence

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- Endometrial Cancers
- Brain and Spinal Cord Neoplasms
- Esophageal and GE Junction Cancers
- Pediatric Liver Cancers
- Plasma Cell Myeloma



The IPMN Path Description must include at least one of the clarifying descriptive terms below:

- IPMN, with high grade dysplasia
- IPMN, non-invasive
- IPMN, in-situ
- IPMN, associated with invasive carcinoma
- IPMN, invasive

- Pancreato-Hepato-Biliary Cancers
- Clarification of Reporting for IPMN and related cancers
- Inconsistency in Reportable Cases of 'high grade dysplasia'

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## New Developments in Cancer Incidence – Endometrial CA

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- **Uterine cancer incidence has been increasing and is projected to surpass colorectal cancer as the third leading cancer and fourth leading cause of cancer death among women by 2040.**
- Endometrioid carcinoma is the predominant histologic subtype, accounting for approximately 75% of all cases that are usually diagnosed at an early stage with good prognosis. These tumors are associated with obesity as well as hormonal and reproductive factors related to cumulative lifetime estrogen exposure.
- Non-endometrioid carcinomas account for approximately 15% to 20% of cases, have been described as estrogen independent and are typically diagnosed at later stages with poorer prognosis.
- **Rates of aggressive non-endometrioid subtypes significantly increased among all women and were twice as high among non-Hispanic Black women compared with other groups for reasons still unclear**
- In a large cohort study of 208,587 women showed increasing uterine cancer mortality is associated with increasing rates of aggressive non-endometrioid carcinomas, but racial and ethnic disparities cannot solely be explained by histologic subtype and stage at diagnosis.
- **Among all women, uterine corpus cancer mortality rates increased significantly by 1.8% per year from 2010 to 2017, as did rates of non-endometrioid carcinomas (2.7%), with increases occurring in Asian (3.4%), Black (3.5%), Hispanic (6.7%) and White women (1.5%).**
- In contrast, endometrioid carcinoma mortality rates remained stable
- Despite stable incidence rates, endometrioid cancer mortality rates have not decreased over the past decade at the population level, suggesting limited progress in treatment for these cancers. The substantial disparities in mortality rates among non-Hispanic Black women cannot be fully explained by subtype distribution and stage at diagnosis.

JAMA Oncol. doi:10.1001/jamaoncol.2022.0009 May 5, 2022. and Obstet Gynecol 2022;139:645–59 DOI: 10.1097/AOG.0000000000004710

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## New Developments in Cancer Incidence – Brain & CNS

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- Brain or spinal cord tumors makeup less than 2% of all cancers diagnosed each year in the United States.
- There are over 130 different types of brain and spinal cord tumors – not all are malignant
- The diversity and rarity of some brain tumors pose unique challenges to developing new treatments.
- Liquid biopsy is helping distinguish between different types of brain tumors more easily in adults
- One specific liquid biopsy test was able to detect a specific genetic alteration in children with genomic changes in DNA shed from medulloblastoma that helped identify kids that had high risk of residual tumor after treatment so they got more aggressive therapy upfront and closer follow-up for relapse.
- Artificial Intelligence is also being used to analyze images to facilitate the classification and diagnosis of brain tumors during surgery and to examine brains for residual tumor following surgical resection
- PARP Inhibitors are being used to treat glioblastoma (Gr IV), astrocytoma (Gr I-III), oligodendroglioma (Gr II-III), medulloblastoma (Gr IV) plus other Gr I-IV neoplasms with IDH1 mutations looking for changes in tumor metabolism
- Other genetics of interest include tumors with BRAF and WNT for gliomas and neurofibromatosis 1
- NCI Brain Tumor Trials Collaborative (BTTC) and NCI-CONNECT Clinical Trial Network 33 centers

Society for Neuro-Oncology, Ichimura et al.: IDH1 mutations in gliomas

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## New Developments in Cancer Incidence – Pediatric Liver

31

- “Hepatoblastomas with carcinoma features represent a biological spectrum of aggressive neoplasms in children and young adults. A high-risk subtype of pediatric ‘**hepatoblastoma with hepatocellular carcinoma features**’ has been discovered using molecular profiling”
- Almost all pediatric liver cancers str classified as either hepatoblastoma or hepatocellular carcinoma.
- However, pediatric pathologists have noted that certain liver tumors have histological characteristics that do not readily match either of these two carcinoma models.
- **They designated these tumor types collectively as HBs with HCC features (HBCs) and outlined histological and molecular characteristics for their classification.**
- The newly described tumors tended to be more resistant to standard chemotherapy and have poor outcomes when not treated with more aggressive surgical approaches, including transplantation.
- Based on the findings, the Baylor College of Medicine Team proposed a diagnostic algorithm to stratify HBCs and guide specialized treatment for these kids as children with HBCs may benefit from treatment strategies that differ from the guidelines for patients with hepatoblastoma and hepatocellular carcinoma

13 May 2022, Journal of Hepatology. DOI: 10.1016/j.jhep.2022.04.035

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## Types of Cancer Screening

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- **Physical Exams** uncover signs of disease, such as lumps, abnormal moles or enlarged organs.
- **Imaging procedures** (mammogram/LDCT/PET/MRI/Ultrasound) take pictures of areas inside the body.
  - A **mammogram** is a screening test for breast cancer. This test is an x-ray picture of the breast. It has been shown to decrease the risk of dying from breast cancer.
  - **Low-dose computed tomography (LDCT)** is used to screen for lung cancer. It has been shown to decrease the risk of dying from lung cancer in heavy smokers. The procedure uses low-dose radiation to make a series of very detailed pictures of areas inside the body using a type of x-ray machine.
- **Direct Observation** involve visual examination of tissue for abnormal growths. A **colonoscopy** is a screening test for colorectal cancer. In this test, the rectum and colon are examined using a flexible lighted tube with a lens for viewing. A colonoscopy can find abnormal colon growths (polyps) in addition to colorectal cancer. An endoscopic ultrasound or EUS combines both direct observation and ultrasound imaging to observe or aid biopsy
- **Laboratory Tests** analyze samples of tissue, blood, urine, or other substances in the body. Cytology, Tumor Marker Testing, Blood and Urine Tests with one exception cannot be used in isolation to diagnose or confirm the presence of cancer (DX Confirmation = 5). ONLY a serum/urine protein electrophoresis test can be assigned 5.
- **Multi-Cancer Early Detection (MCED) Tests** are tests that measure molecular biomarkers or tumor markers in body fluids that may be shed by cancer cells. Currently, no MCED Tests are approved by FDA just yet. Tests can assess a few or hundreds of molecular, genetic, protein, or other tumor markers all at once in a panel.

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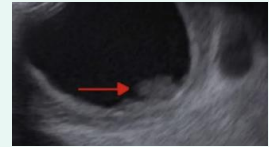


## New Developments in Cancer Screening

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### Targeted Screening Programs for pancreato-hepato-biliary cancers

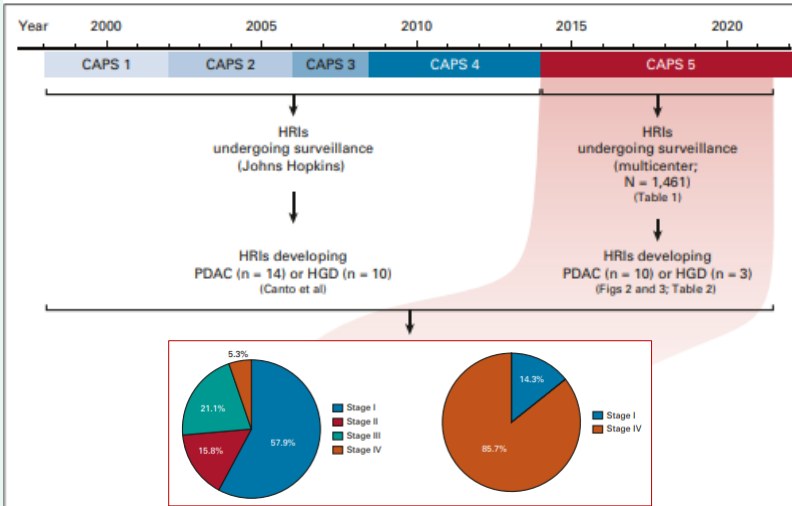
- Early detection of tumor or precursor lesions with dysplasia the most effective approach to improve survival
- Use of Endoscopic Ultrasound (EUS) or MRI Cholangiopancreatography (MRCP) -- with or without biopsy
- Some Centers Started Identifying High-Risk Populations and Began Screening Programs in 2016
- High-Risk Population Screening – male, black, Ashkenazi Jewish descent, obesity, smoking, diabetes
- Hereditary Factors (BRCA2, HNPCC, BRCA1, cystic fibrosis, FAP) and Familial Pancreatic Cancer (FPC)
- Personal History of Pancreatitis – acute, chronic, multiple episodes
- Per SEER Instruction - Must do a biopsy that shows one or more of the following
  - ✦ PanIN3 – Pancreatic Intraepithelial Neoplasia Grade 3
  - ✦ High grade dysplasia
  - ✦ Carcinoma in-situ
  - ✦ Invasive carcinoma
- If they don't do a biopsy – abnormality or clinical dx of malignant IPMN – the case is not reported
- This is problematic since many of these patients may go on to have treatment even a Whipple
- Novel techniques such as needle-based confocal laser endomicroscopy (nCLE), along with biomarkers, may be helpful to identify pancreatic lesions with more aggressive malignant potential.
- We are also seeing this condition in other branch ducts of biliary system and hepatic duct system
- These are mucinous and ductal carcinomas – non-invasive and early invasive



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## New Developments in Cancer Screening

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High-Risk Cohort	N = 1,461
Age, mean ± SD, years	60.3 ± 9.7
Sex (female), No. (%)	944 (64.6)
Race/ethnicity, No. (%)	
White	1,380 (94.5)
African American	51 (3.5)
Asian	19 (1.3)
Hispanic/Latino	35 (2.4)
Other/multiple	13 (0.7)
Pathogenic germline variant carriers, No. (%)	
BRCA2 + ≥ 1 FDR/SDR with PDAC	269 (18.4)
BRCA1 + ≥ 1 FDR with PDAC	68 (4.7)
CDKN2A (FAMMM syndrome)	69 (4.7)
Lynch syndrome + ≥ 1 FDR/SDR with PDAC	58 (4.0)
PALB2 + ≥ 1 FDR/SDR with PDAC	62 (4.2)
ATM + ≥ 1 FDR/SDR with PDAC	93 (6.4)
Peutz-Jeghers syndrome (STK11)	18 (1.2)
More than one mutation + ≥ 1 FDR/SDR with PDAC	6 (0.4)
Familial pancreatic cancer without known pathogenic germline variants, No. (%)	
≥ 2 FDR <sup>a</sup>	346 (23.7)
1 FDR + ≥ 1 SDR <sup>b</sup>	402 (27.5)
1 FDR with young onset PDAC ≤ 50 years old	5 (0.3)
Other high-risk cohort (Data Supplement), No. (%)	65 (4.5)
Personal history of cancer, <sup>c</sup> No. (%)	455 (31.1)
Smoking, No. (%)	
Never/former	910/1,420 (64.1)/454 (32.0)
Current	56 (3.9)
Alcohol use (current), No. (%)	733/1,414 (51.8)
Diabetes mellitus (type 1/2), No. (%)	137/1,391 (9.8)

<http://ascopubs.org/journal/jco>

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## New Developments in Cancer Screening

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**TABLE 1. Summary of population, intervention, comparator, and outcomes questions**

Question	Population	Intervention	Comparator	Outcomes	Rating
1	Individuals at increased risk of pancreatic cancer because of genetic susceptibility	Screening	No screening	All-cause mortality	Critical
2	Individuals at increased risk of pancreatic cancer because of genetic susceptibility undergoing screening	Magnetic resonance imaging	EUS	Pancreatic cancer mortality	Critical
3a	Individuals with <i>BRCA2</i> pathogenic variant*	Screening	No screening	Cumulative yield of screening	Critical
3b	Individuals with <i>BRCA1</i> pathogenic variant*	Screening	No screening	Detection of resectable and borderline-resectable lesions Psychological benefits Harms	Important Critical

**TABLE 2. Summary of additional management questions addressed in the guideline using non-Grading of Recommendations Assessment, Development and Evaluation methodology**

Question	Population	Management question
4	Individuals at increased risk of pancreatic cancer because of genetic susceptibility	How often should screening for pancreatic cancer be performed?
5	Individuals at increased risk of pancreatic cancer because of genetic susceptibility undergoing screening a) <i>BRCA2</i> pathogenic variant b) <i>BRCA1</i> pathogenic variant c) <i>PALB2</i> pathogenic variant d) Familial pancreatic cancer e) Familial atypical multiple mole melanoma syndrome f) Peutz-Jeghers syndrome g) Ataxia-telangiectasia mutated heterozygotes with first- or second-degree relative with pancreatic cancer h) Lynch syndrome with first- or second-degree relative with pancreatic cancer i) hereditary pancreatitis	At what age should screening for pancreatic cancer start?

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## New Developments in Tumor Classification & Biomarker Testing

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- Tumor Tissue Markers – sample of the tumor
- Circulating Tumor Markers – blood, urine, stool, body fluids
- Colorectal Cancer ctDNA Testing – tests for single DNA abnormality
- OncotypeDX – breast, colon, noninvasive breast – just a few genes in testing
- Leukemia Panel Testing for Subtype of Leukemia
- Liquid Biopsy FDA-Approved Assays – August 2020 – for solid tumors only
  - Guardant 360 CDx – 74 genes and other biomarkers
  - FoundationOne Liquid CDx – 324 genes and MSI
  - Caris Life Sciences – 592 Genes (not FDA Approved yet)
- Multi-Cancer Early Detection (MCED) Assays – a subset of liquid biopsy tests
  - Changes in DNA and/or RNA sequences,
  - Patterns of DNA methylation (a chemical change to DNA),
  - Patterns of DNA fragmentation (how the DNA is broken into smaller pieces),
  - Levels of protein biomarkers, and
  - Antibodies that a person may develop against components of growing cancer cells.

**LIQUID BIOPSY**

A new, noninvasive technique that can detect disease biomarkers in:

BLOOD

URINE

SPUTUM

**LIQUID BIOPSY IS USEFUL WHEN:**

- not enough tissue sample is available
- not enough tumor tissue is in a sample
- a tumor is hard to reach
- regular monitoring is needed

**LIQUID BIOPSIES ARE ANALYZED FOR:**

- presence of cancer cells
- DNA
- other substances released by tumors

cancer.gov

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## New Developments in Tumor Classification & Biomarker Testing

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- Need to know what the molecular biomarker or tumor marker is for:
- Molecular Biomarker Testing for Risk Assessment
- Molecular Biomarker Testing for Confirmation of Disease
- Molecular Biomarker Testing for Diagnostic Workup & Extent of Disease
- Molecular Biomarker Testing for (Sub)Classification of Neoplasm
- Molecular Biomarker Testing for Treatment Choices
- Other and To Be Determined Uses



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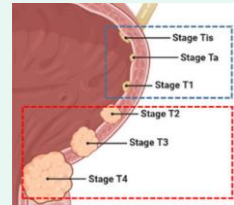
- **Histology** – Microscopy examines the microanatomy of cells, tissues, and organs as seen through a microscope – physical characteristics. It examines the correlation between structure and function.
- **Biologic Tumor Marker** – Immunoassay can be used to identify anything present in or produced by cancer cells or other cells from blood, urine and body fluids. Tumor Markers provide information about a cancer, aggressiveness, what kind of treatment it may respond to, or whether it is responding to treatment. Tumor markers can be proteins, conjugated proteins, peptides and carbohydrates.
- **Immunohistochemistry** – a microscopy-based technique that allows selective identification and localization of antigens in cells. IHC selectively identifies antigens (proteins) in cells from tissue by exploiting the principle of antibodies binding specifically to antigens in biological tissues. IHC uses light or fluorescent microscopy to analyze results. IHC is less expensive than flow cytometry.
- **Flow Cytometry** – a laser-based technique that detects and measures the physical and chemical characteristics of a cell population. Flow cytometry can be used to count and sort cells (identify proliferation of cells and type), determine cell characteristics, identify biomarkers and to diagnose/classify certain cancers. It is more precise metric for antigens than histology or IHC testing.
- **Cluster of Differentiation (CD) Molecules** – cell surface molecules used to classify white blood cells that are especially important for diagnosis of lymphomas and leukemias. CD marker antibodies have been widely used for cell sorting, phenotyping, and blood cancer diagnosis and for treatment.
- **Immunophenotype** – uses the CD system to define markers associated with specific cells or conditions
- **Cytogenetics** - involves testing samples of tissue, blood, or bone marrow in a laboratory to look for changes in chromosomes, including broken, missing, rearranged, or extra chromosomes. Changes in certain chromosomes may be a sign of a genetic disease or condition or some types of cancer. FISH is common cytogenetics test.
- **DNA Microarray** – used to study the extent to which certain genes are turned on or off in cells and tissues. It is used to identify the changes in gene sequences that are most often associated with a particular disease.
- **Next Generation Sequencing** – a large-scale DNA and RNA sequencing technology to determine the order of nucleotides in entire genomes or targeted regions of DNA or RNA in cells and tissues.

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## New Developments in Diagnostic Tools & Cancer Treatments

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- Erdafitinib (Balversa) the first mutation-targeted bladder cancer drug is being underused
- The drug was approved by the U.S. Food and Drug Administration (FDA) in early 2019.
- About 20% of advanced urothelial carcinomas are driven by mutations that cause growth-related receptors called FGFRs (Fibroblast Growth Factor Receptors) to be overactive.
- Erdafitinib works as an inhibitor of FGFR activity. It is meant to be used in patients who have susceptible FGFR mutations and are no longer responding to standard chemotherapy.
- A large, nationwide database of cancer cases was examined by researchers at the University of Pennsylvania. Between 2019 and 2021, in a sample of nearly 800 bladder cancer patients potentially eligible for treatment, fewer than half had a record of being tested for the relevant gene mutation.
- Of those tested and found to have the mutation, fewer than half received treatment.
- 81,000 Americans are diagnosed with bladder cancer each year – 7/8 are men.
- About 17,000 people die from the disease annually.
- The five-year survival rate is about 77 percent
- Genetic testing needs to be more widely available for patients to learn about and access, and education for treating physicians is a must so they can gain knowledge on the benefits and value in use for eligible patients



JAMAOncol.2022;8(7):10701072.doi:10.1001/jamaoncol.2022.1167

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## New Developments in Diagnostic Tools & Cancer Treatments

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- Flash Therapy – A REVOLUTION in Therapy
  - Rather than days or weeks of fractions of radiation given to a patient, the entire massive dose is delivered all at once very quickly in one fraction sparing normal tissue
  - Deliver radiation therapy at flash dose rates 100 times what we would normally
- Image-Guided Radiotherapy Systems
  - MRI-Guided Linear Accelerators – real-time ‘dynamic’ imaging during radiation
    - ✦ Two Systems Currently Available: Elekta Unity and Viewray MRIdian Systems
  - PET Radiotracer Detectors can image metastases targeting each one in real-time
    - ✦ Reflexion PET-targeting adaptive therapy technology
- Proton Therapy now considered a Mainstream Treatment Option
- PSMA (prostate-specific membrane antigen) PET imaging w/68Ga-PSAM-11
- Synthetic CT from MRI converts MRI datasets into synthetic CT image datasets for use in planning process eliminating need for a separate CT Scan
- Artificial Intelligence in Radiotherapy - Increasing Speed of Treatment Planning Systems and the Integration of Artificial Intelligence
- A new ASTRO Guide to Managing Primary Brain Tumors and Brain Metastases

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## New Developments in Diagnostic Tools & Cancer Treatments

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- Disguising Cancer as an Infection Helps the Immune System Eliminate Tumors
- Although the immune system can pack a powerful punch against cancer, many tumors find ways to turn off or block immune cells.
- But NCI researchers may have found a clever way to give immune cells the upper hand—by disguising the cancer as a viral infection.
- Injected bits of viral proteins, called peptides, coat the outsides of cancer cells
- “So, you are fooling the immune system into thinking, ‘I have this big virus infection, I better go attack it,’” Dr. Schiller said.
- The viral peptides catch immune cells' attention and unleash an attack but don't actually cause an infection – CMV Immunotherapy – still experimental but highly promising
- Researchers used peptides from Cytomegalovirus (CMV), a virus that most people's immune systems have seen before. Around 5 out of 10 people in the United States and 8 out of 10 worldwide are infected with CMV, and it usually doesn't cause any symptoms.
- Findings published June 24 in the *Proceedings of the National Academy of Sciences*  
<https://www.cancer.gov/news-events/cancer-currents-blog/2022/cancer-immunotherapy-cmv-peptides>

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## New Developments in Diagnostic Tools & Cancer Treatments

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- New image-based model may inform 'how aggressively a lung cancer should be treated'
- Lung cancer screening identifies cancers at early and presumably more treatable stages and can improve overall mortality rates for lung cancer. There is always a possibility of overdiagnosis and overtreatment in patients with screen-detected tumors.
- Overdiagnosis of pulmonary nodules can result in unnecessary diagnostic procedures that are often invasive, associated with increased costs, and associated with added stress for patients and their families. In the National Lung Screening Trial (NLST), 10 to 27% lung cancers were over-diagnosed.
- NLST created a repository of thousands of CT and Path images available from NCI for researchers to use in study.
- Using images and data from the NLST CT Repository, Moffitt Cancer Center in Tampa, Florida has developed an image-based model based on intra-tumor radiomics and volume doubling time (VDT) to help identify high-risk versus low-risk tumors that could inform how aggressively lung cancers should be treated.
- Pulmonary nodules that are of an infectious or inflammatory pathophysiology have a VDT of less than 20 days, a VDT of less than 400 days (and greater than 20 days) represents a high likelihood of malignancy, and a VDT above 500 days is likely a benign nodule.
- Furthermore, not all early stages are the same. There is a spectrum of intermediate-risk cancers as well. And some early-stage cancers can be very aggressive with poor outcomes that require aggressive treatment and adjuvant therapies. This model helps distinguish between them.
- The radiomic model used NLST data to establish 65 stable and reproducible features including; volume doubling time of lung nodules, volume doubling time cut-off points, radio-genomics, tumor genomics, biomarkers, histology, tumor location, patient characteristics, screening interval, smoking status, compactness of nodule, tumor boundary, tumor edges, roundness, and other factors were input to the model to predict tumor behavior of screen-detected lung cancers. These in turn were used to guide treatment decisions and timing of treatment based on the model.

Pérez-Morales, Jaileene et al. 'Volume Doubling Time and Radiomic Features Predict Tumor Behavior of Screen-detected Lung Cancers'. 1 Jan. 2022 : 489 – 501. Cancer Biomarkers, vol. 33, no. 4, pp. 489-501, 2022

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## Update on Effects of the COVID-19 Pandemic

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- According to a new study led by the American Cancer Society, the COVID-19 Pandemic increased the number of cancer-related deaths by 3.2% in the United States from 2019- 2020.
- The results showed the number of cancer-related deaths was 686,054 in 2020, up from 664,888 in 2019, with an annual increase of 3.2%.
- Compared to the number of projected deaths for 2020 (666,286), the number of cancer-related excess deaths was 19,768 in 2020.
- Furthermore, NCI reported that COVID-19 was third leading cause of death in the United States in both 2020 and 2021. The study appeared in JAMA Internal Medicine on 7/5/2022
- The pandemic prevented many people from getting regular cancer screening, which may result in future increases in cancer deaths with people reluctant to seek care for fear of catching COVID-19.
- During the 20-month period studied, COVID-19 accounted for 1 in 8 deaths (or 350,000 deaths) in the United States. Heart disease was the number one cause of death, followed by cancer, with these two causes of death accounting for a total of 1.29 million deaths.
- Every age group 15 years and up, COVID-19 was one of the top five causes of death during the period.

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## Update on Effects of the COVID-19 Pandemic

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Cancer case trends following the onset of the COVID-19 pandemic: A community-based observational study with extended follow-up

Charles W. Drescher, MD<sup>1,2</sup>; Adam J. Bograd, MD<sup>3</sup>; Shu-Ching Chang, PhD<sup>2</sup>; Roshanithi K. Weerasinghe, MPH<sup>4</sup>; Ann Vita<sup>4</sup>; and R. Bryan Bell, MD<sup>5</sup>



This cross-sectional study retrospectively analyzed the electronic medical records of 80,138 cancer patients diagnosed between January 1, 2019, and May 31, 2021. Outcome measures included weekly number of new cancer cases and trends in weekly cancer cases, before and after the pandemic; patient demographics; and positive COVID-19 test rates.

Beginning March 4, 2020, defined as the onset of the pandemic, weekly cancer cases declined precipitously (–110.0 cases per week) for 4 weeks, followed by a moderate recovery (+23.7 cases per week of 10 weeks duration). Thereafter, weekly cancer cases trended slowly back toward pre-COVID- 19 baseline levels.

Following the pandemic onset, there was a cumulative year-over-year decline in cancer cases overall of 7.3%, including a 20.2%, 14.3%, and 12.8% decline in nonmelanoma skin cancer, breast cancer, and prostate cancer.

The data in this study demonstrate a substantial reduction in cancer diagnoses following the onset of COVID-19, Which appear to reach expected pre-COVID norms 12 months later. The largest reduction was noted among cancers that are typically screen-detected or identified as part of a routine wellness examination.

Cancer 2022;128:1475-1482. © 2021 American Cancer Society.

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## Update on Cancer Moonshot

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- President Biden Reignites Cancer Moonshot to Speed Progress
- Administration Sets Goal of Reducing Cancer Death Rate by at least 50% over the next 25 Years and improve the experience of people and their families living with and surviving cancer to end cancer as we know it today.
- Call to Action on Cancer Screening and increased funding for NIH/NCI
- The new Cancer Moonshot initiative will include a White House Cancer Moonshot coordinator in the Executive Office of the President; a Cancer Cabinet which will unite all the major government agencies, not just those that specialize in health, and a major effort to get cancer screenings back on track.
- The President wants to establish an Advanced Research Projects Agency for Health (ARPA-H), which would be housed within the NIH and would be modeled on the Defense Advanced Research Projects Agency (DARPA), which produced the Internet and self-driving cars.

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# Questions

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