

The Room Where It Happens: A Behind the Scenes Look at the NCCN Guidelines Development Process



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Session Learning Objectives

- Explain the common considerations and approaches used by NCCN Guidelines panels when updating or developing NCCN Guidelines recommendations.
- Describe how panels apply the NCCN Categories of Evidence and Consensus and the NCCN Categories of Preference to recommendations within NCCN Guidelines.
- Delineate the ways in which NCCN manages conflict of interest and bias among Guidelines panel members.

The Room Where It Happens: A Behind the Scenes Look at the NCCN Guidelines Development Process



Deborah A. Freedman-Cass, PhD
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NCCN Clinical Practice Guidelines in Oncology

Treatment by Cancer Type

Detection, Prevention,
and Risk Reduction

Supportive Care

Specific Populations

Acute Lymphoblastic Leukemia
Version: 3.2024

Acute Myeloid Leukemia
Version: 2.2025

Ampullary Adenocarcinoma
Version: 2.2025

Anal Carcinoma
Version: 2.2025

Basal Cell Skin Cancer
Version: 2.2025

B-Cell Lymphomas
Version: 2.2025

Biliary Tract Cancers
Version: 6.2024

Bladder Cancer
Version: 7.2024

Bone Cancer
Version: 2.2025

Breast Cancer
Version: 1.2025

Castleman Disease
Version: 2.2025

Central Nervous System Cancers
Version: 4.2024

Cervical Cancer
Version: 3.2025

Chronic Lymphocytic Leukemia/Small
Lymphocytic Lymphoma
Version: 2.2025

Chronic Myeloid Leukemia
Version: 3.2025

Colon Cancer
Version: 1.2025

Dermatofibrosarcoma Protuberans
Version: 1.2025

Esophageal and Esophagogastric Junction
Cancers
Version: 1.2025

Gastric Cancer
Version: 5.2024

Gastrointestinal Stromal Tumors
Version: 2.2024

Gestational Trophoblastic Neoplasia
Version: 2.2025

Hairy Cell Leukemia
Version: 1.2025

Head and Neck Cancers
Version: 2.2025

Hepatobiliary Cancers
Version: 1.2023

Hepatocellular Carcinoma
Version: 4.2024

Histiocytic Neoplasms
Version: 3.2024

Hodgkin Lymphoma
Version: 2.2025

Kaposi Sarcoma
Version: 2.2025

Kidney Cancer
Version: 3.2025

Melanoma: Cutaneous
Version: 2.2025

Melanoma: Uveal
Version: 1.2025

Merkel Cell Carcinoma
Version: 1.2025

Mesothelioma: Peritoneal
Version: 2.2025

Mesothelioma: Pleural
Version: 2.2025

Multiple Myeloma
Version: 1.2025

Myelodysplastic Syndromes
Version: 2.2025

Myeloid/Lymphoid Neoplasms with
Eosinophilia and Tyrosine Kinase Gene
Fusions
Version: 1.2025

Myeloproliferative Neoplasms
Version: 1.2025

Neuroblastoma
Version: 2.2024

Neuroendocrine and Adrenal Tumors
Version: 4.2024

Non-Small Cell Lung Cancer
Version: 3.2025

Occult Primary
Version: 2.2025

Ovarian Cancer/Fallopian Tube
Cancer/Primary Peritoneal Cancer
Version: 3.2024

Pancreatic Adenocarcinoma
Version: 2.2025

Pediatric Acute Lymphoblastic Leukemia
Version: 2.2025

Pediatric Aggressive Mature B-Cell
Lymphomas
Version: 2.2024

Pediatric Central Nervous System Cancers
Version: 2.2025

Pediatric Hodgkin Lymphoma
Version: 1.2024

Penile Cancer
Version: 2.2025

Primary Cutaneous Lymphomas
Version: 1.2025

Prostate Cancer
Version: 1.2025

Rectal Cancer
Version: 1.2025

Small Bowel Adenocarcinoma
Version: 2.2025

Small Cell Lung Cancer
Version: 2.2025

Soft Tissue Sarcoma
Version: 4.2024

Squamous Cell Skin Cancer
Version: 2.2025

Systemic Light Chain Amyloidosis
Version: 1.2025

Systemic Mastocytosis
Version: 1.2025

T-Cell Lymphomas
Version: 1.2025

Testicular Cancer
Version: 1.2025

Thymomas and Thymic Carcinomas
Version: 1.2025

Thyroid Carcinoma
Version: 5.2024

Uterine Neoplasms
Version: 2.2025

Vaginal Cancer
Version: 5.2025

Vulvar Cancer
Version: 1.2025

Waldenström
Macroglobulinemia/Lymphoplasmacytic
Lymphoma
Version: 3.2025

Wilms Tumor (Nephroblastoma)
Version: 2.2024

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NCCN Clinical Practice Guidelines in Oncology

Treatment by Cancer Type

Detection, Prevention, and Risk Reduction

Supportive Care

Specific Populations

Breast Cancer Risk Reduction

Version: 2.2025

Breast Cancer Screening and Diagnosis

Version: 2.2024

Colorectal Cancer Screening

Version: 1.2024

Genetic/Familial High-Risk Assessment: Breast, Ovarian, Pancreatic, and Prostate

Version: 2.2025

Genetic/Familial High-Risk Assessment: Colorectal, Endometrial, and Gastric

Version: 3.2024

Lung Cancer Screening

Version: 1.2025

Prostate Cancer Early Detection

Version: 2.2024

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NCCN Clinical Practice Guidelines in Oncology

Treatment by Cancer Type

Detection, Prevention, and Risk Reduction

Supportive Care

Specific Populations

Adult Cancer Pain

Version: 3.2024

Antiemesis

Version: 2.2024

Cancer-Associated Venous Thromboembolic Disease

Version: 1.2025

Cancer-Related Fatigue

Version: 2.2025

Distress Management

Version: 1.2025

Hematopoietic Cell Transplantation

Version: 1.2025

Hematopoietic Growth Factors

Version: 1.2025

Management of Immunotherapy-Related Toxicities

Version: 1.2025

Palliative Care

Version: 1.2025

Prevention and Treatment of Cancer- Related Infections

Version: 3.2024

Smoking Cessation

Version: 2.2024

Survivorship

Version: 2.2024

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NCCN Clinical Practice Guidelines in Oncology

Treatment by Cancer Type

Detection, Prevention, and Risk Reduction

Supportive Care

Specific Populations

Adolescent and Young Adult (AYA) Oncology

Version: 2.2025

Older Adult Oncology

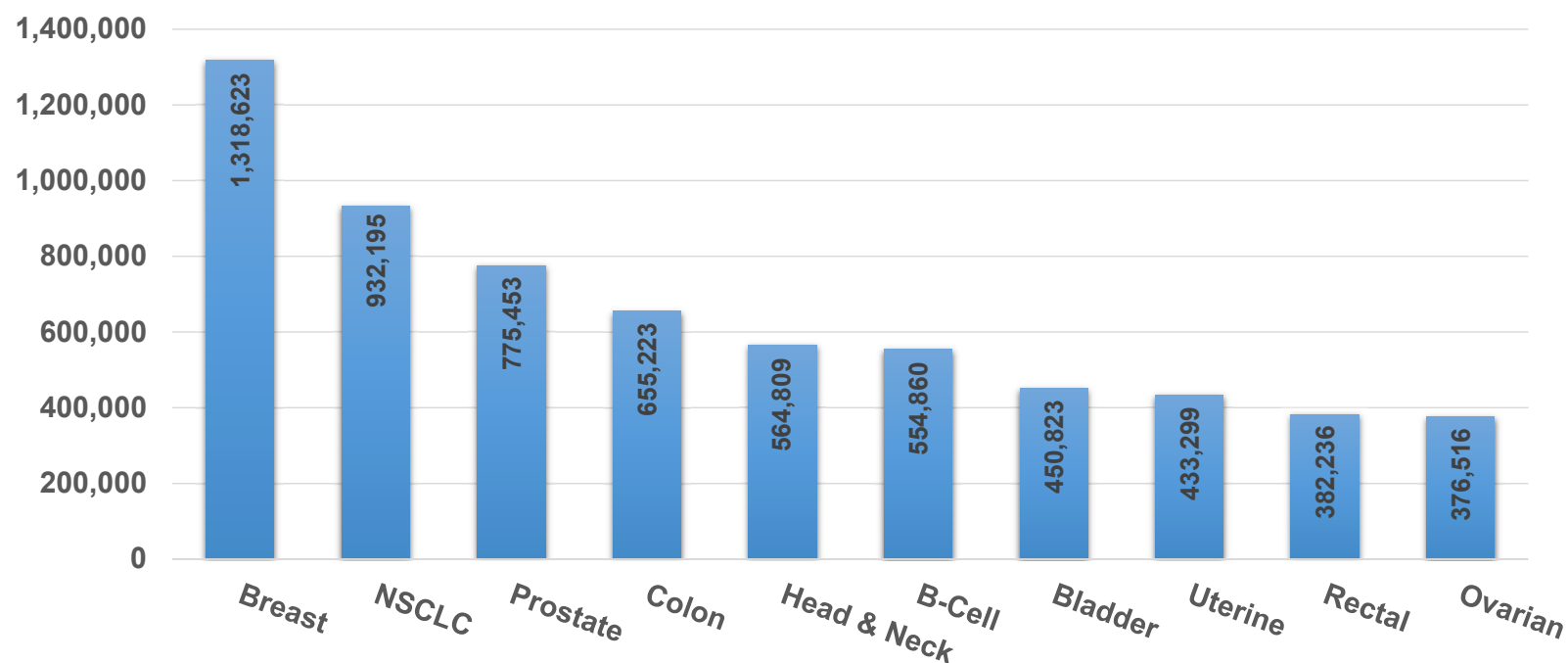
Version: 1.2025

Cancer in People with HIV

Version: 1.2025

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NCCN Guidelines – Top 10 Downloads in 2024



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NCCN Guidelines – Key Contributors

- **NCCN Guidelines Steering Committee**

- comprises 1 representative from each NCCN Member Institution
- oversees the processes and planning of the NCCN Guidelines
- appoints representatives to each Guidelines Panel, typically in consultation with Panel leadership



- **NCCN Guidelines Panel Chair and Vice Chair (Panel Leadership)**

- selected by the leadership of NCCN and the NCCN Guidelines Team, typically in consultation with the current panel leadership
- help ensure the inclusion and participation of relevant clinical expertise within their Panels
- plan the agenda for and preside over Panel meetings
- oversee content development activities pertaining to the specific Panel

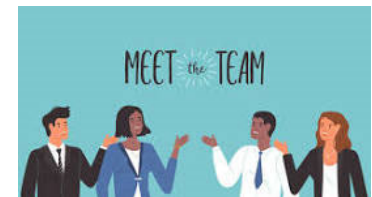
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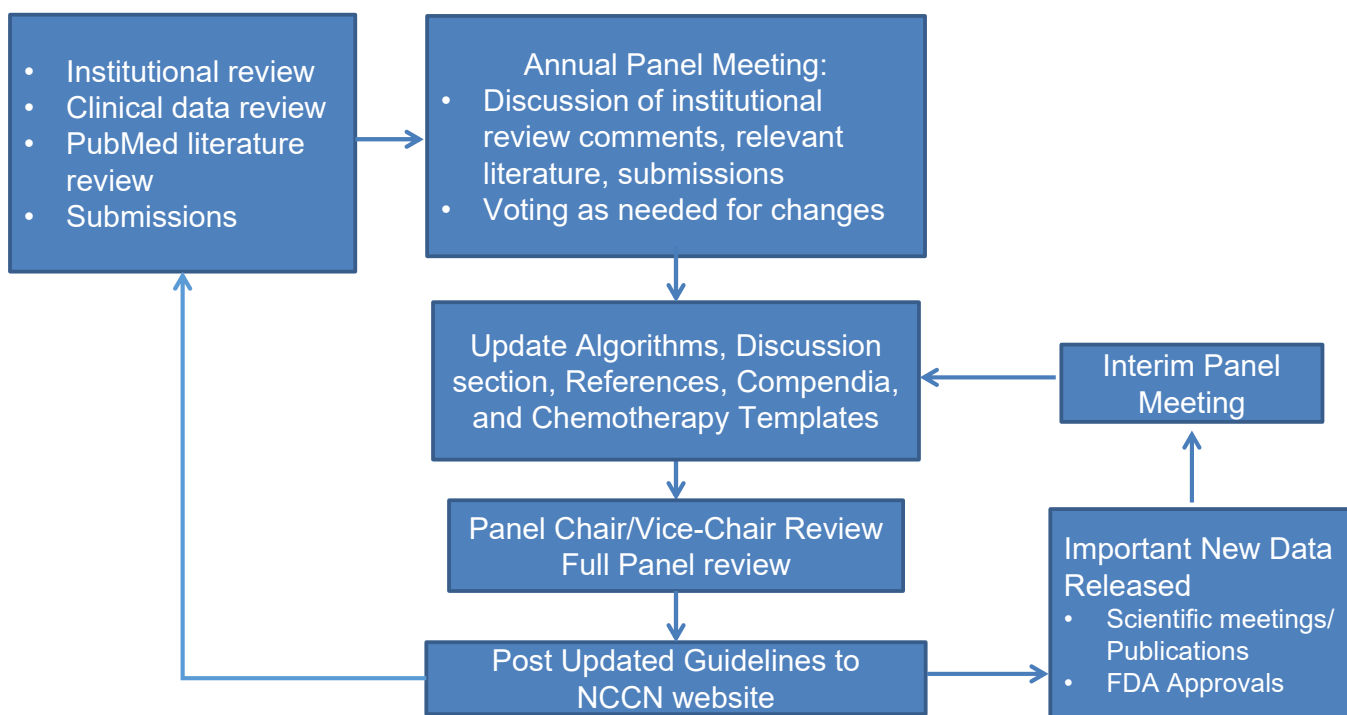
NCCN Guidelines – Key Contributors (cont.)

- **NCCN Guidelines Panel Members**
 - represent their institutions for Panel reviews, deliberations, votes
 - may present data relevant to agenda topics
 - a patient advocate is included as full members of each Panel whenever possible
- **NCCN Guidelines Team**
 - comprises administrative support staff, copyeditors, oncology scientists/writers, coordinators/layout specialists, and the leadership of the NCCN Guidelines Team
 - provides planning, development, and procedural support
 - works in close collaboration with the Panel to develop and update the Guidelines to reflect Panel recommendations



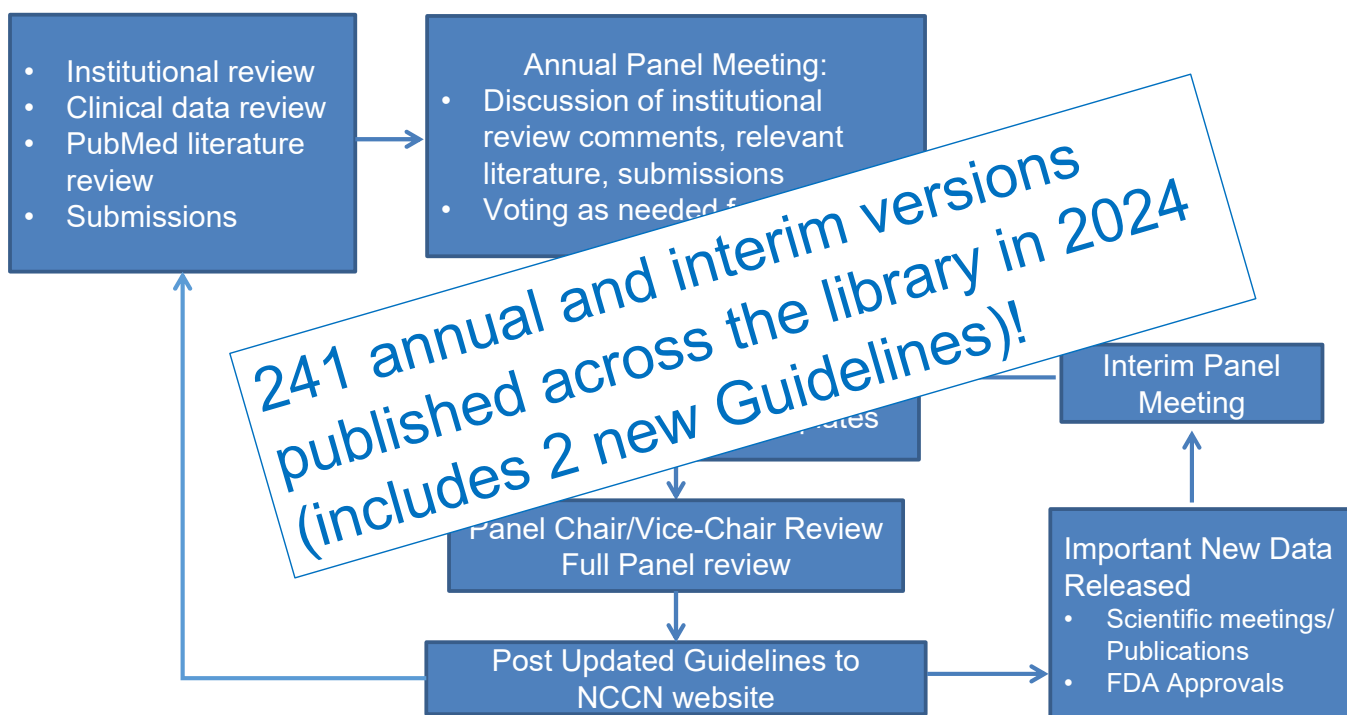
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NCCN Guidelines Update Process



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NCCN Guidelines Update Process



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Payor Coverage



- Well over 85% of Americans are covered by plans that utilize NCCN Guidelines
- Most plans cover Category 1 and 2A recommendations; some cover 2B
- Payor coverage based on rigor of NCCN processes
 - Critical review of evidence + clinical expertise and consensus of a multidisciplinary panel of experts
 - Credibility (strict firewall)
 - Transparency
 - Avoidance of bias

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NCCN Categories of Evidence and Consensus

NCCN Categories of Evidence and Consensus	
Category 1	Based upon high-level evidence (≥1 randomized phase 3 trials or high-quality, robust meta-analyses), there is uniform NCCN consensus (≥85% support of the Panel) that the intervention is appropriate.
Category 2A	Based upon lower-level evidence, there is uniform NCCN consensus (≥85% support of the Panel) that the intervention is appropriate.
Category 2B	Based upon lower-level evidence, there is NCCN consensus (≥50%, but <85% support of the Panel) that the intervention is appropriate.
Category 3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

All recommendations are category 2A unless otherwise indicated.

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NCCN Categories of Preference

NCCN Categories of Preference	
Preferred intervention	Interventions that are based on superior efficacy, safety, and evidence; and, when appropriate, affordability.
Other recommended intervention	Other interventions that may be somewhat less efficacious, more toxic, or based on less mature data; or significantly less affordable for similar outcomes.
Useful in certain circumstances	Other interventions that may be used for selected patient populations (defined with recommendation).

All recommendations are considered appropriate.

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NCCN Guidelines Credibility

- The Guidelines development process is funded by Member Institution dues
 - No industry funds or other external financial support is used
- Industry representatives are not allowed to attend meetings
- Panel Members and NCCN Guidelines Team Members should not be contacted to solicit or suggest changes to Guidelines content
 - Submission process should be used



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NCCN Guidelines Transparency

- The following are published at the NCCN website:
 - Annual meeting dates
 - Guidelines development process
 - Disclosure policy
 - Panel Members/NCCN staff for each Guideline
 - Disclosures for Panel Members and NCCN staff
 - Aggregate Panel votes
 - All submissions received



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Managing Conflicts of Interest

- Many experts and clinical researchers have relationships with industry (eg, funding for clinical or basic research, compensation for advisory board participation)
 - These activities can further scientific knowledge, facilitate and accelerate the development of new treatments, and educate those in industry and academia
 - However, financial relationships with industry have the potential to introduce conflicts of interest and biases into the NCCN Guidelines development process



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Managing Conflicts of Interest – Disclosure

- All involved in the Guidelines development process must review and confirm disclosure information every 6 months
- Panel Chairs/Vice Chairs cannot participate in non-scientific activities (promotional, marketing, speakers bureau)
- All Panel Members receive disclosure information for everyone on the panel before each Panel meeting
- Monitoring is through self disclosure and annual review of CMS Open Payments data



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Managing Conflicts of Interest – Disclosure

- **Financial thresholds** – payment and/or equity (panel member + spouse/domestic partner + dependent children)
 - \$20,000 – individual
 - \$50,000 – aggregate
- **Not included**
 - Clinical trial support funds received by the panel member's institution
 - Support from governmental agencies (eg, NIH, DOD, CDC)
 - Participation on official Data Safety Monitoring Boards
 - Honoraria from accredited educational programs



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Managing Conflicts of Interest – Abstention

Abstaining from Panel Discussion

- When there is a direct or indirect relationship with the organization that owns the agent/device/test being discussed (equity, compensation, patent, employee/officer)



Abstaining from Panel Vote

- When there is a direct or indirect relationship with the organization that owns the agent/device/test being discussed (equity, compensation, patent, employee/officer)
- National Principal Investigator on a clinical trial involving the agent/device/test

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NCCN Guidelines - Confidentiality

- Implications for changes within the Guidelines
- Only Panel Members and NCCN staff participate in panel meetings
- Any potential Guidelines revisions are considered confidential and not to be discussed outside of the Panel until publication
- NCCN is subject to Department of Justice and Securities and Exchange Commission (SEC) reviews



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NCCN Global Clinical Content

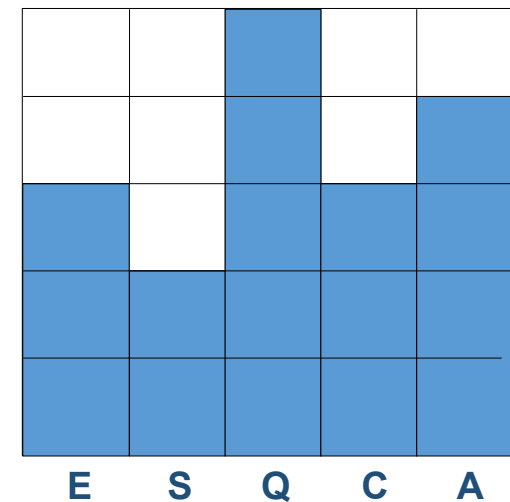


- Framework for Resource Stratification
- Adaptations (Brazil, China, Middle East and North Africa, Poland, Spain, Sub-Saharan Africa, and Vietnam)
- Translations (eg, Chinese, Portuguese, Spanish)

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NCCN Evidence Blocks

- Visual display to inform decision-making
- Panels vote on 5 measures for each regimen
 - Efficacy
 - Safety
 - Quality of Evidence
 - Consistency of Evidence
 - Affordability
- Allows individualized assessment of value



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NCCN Clinical Information Products

- **NCCN Guidelines Derivative Products**
 - Drugs and Biologics Compendium
 - Biomarkers Compendium
 - Imaging Appropriate Use Criteria
 - Radiation Oncology Compendium
 - Chemotherapy Order Templates
 - JNCCN
 - Patient Guidelines



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NCCN Member Institutions



Who We Are

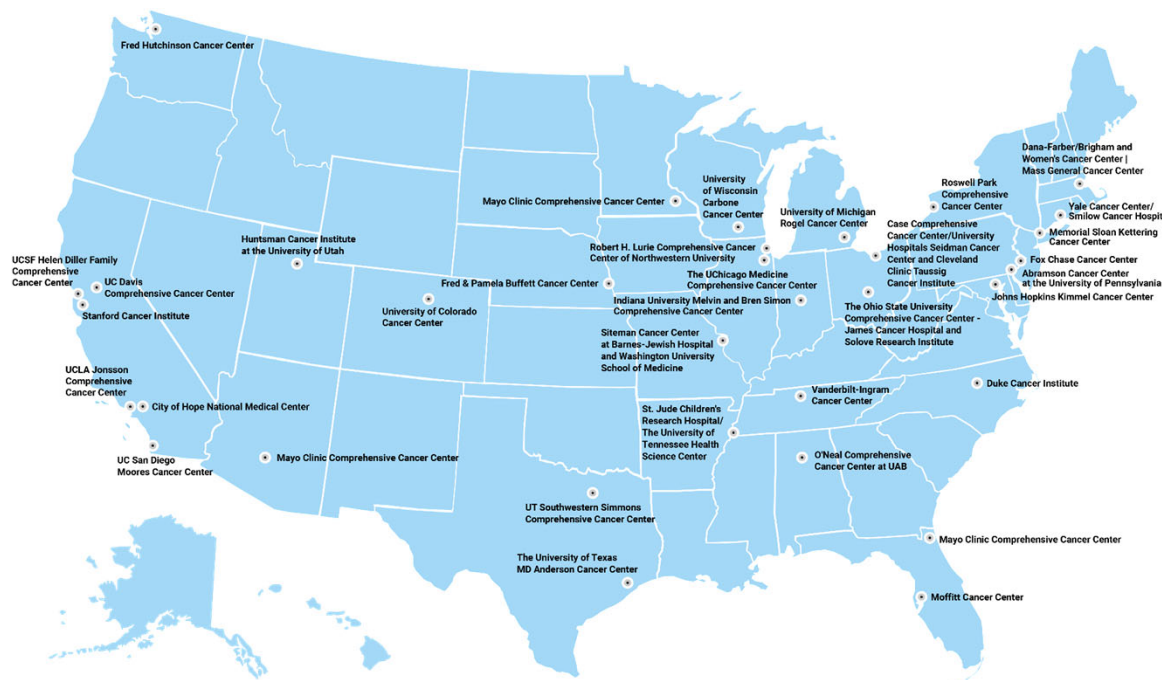
An alliance of leading cancer centers devoted to patient care, research, and education

Our Mission

To define and advance quality, effective, equitable, and accessible cancer care and prevention so all people can live better lives

Our Vision

Access to high-quality, high-value, patient-centered cancer care for all people globally



[NCCN.org](https://www.nccn.org) – For Clinicians | [NCCN.org/patients](https://www.nccn.org/patients) – For Patients | [Education.nccn.org](https://www.education.nccn.org) – CE Portal