NCCN Clinical Practice Guidelines® Development Process

Robert W. Carlson, M.D.
CEO, National Comprehensive Cancer Network
Professor of Medicine, Emeritus
Stanford University
Adjunct Professor of Medical Oncology
Fox Chase Cancer Center

Quality Health Care

Quality of health care is the degree to which health services for individuals and populations increase the likelihood of desired outcomes and are consistent with current professional knowledge.

Institute of Medicine, 1990

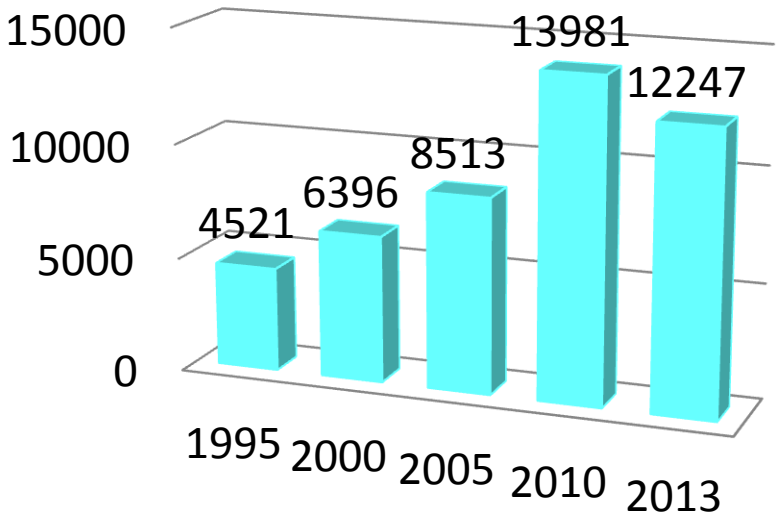
Clinical Practice Guidelines

Systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.

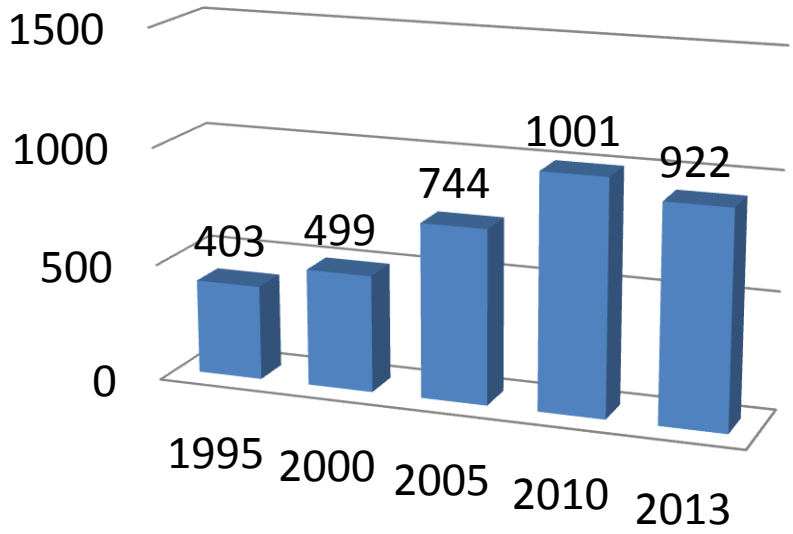
Institute of Medicine, 1990

PubMed Breast Cancer Publications

All Publications



Clinical Trials



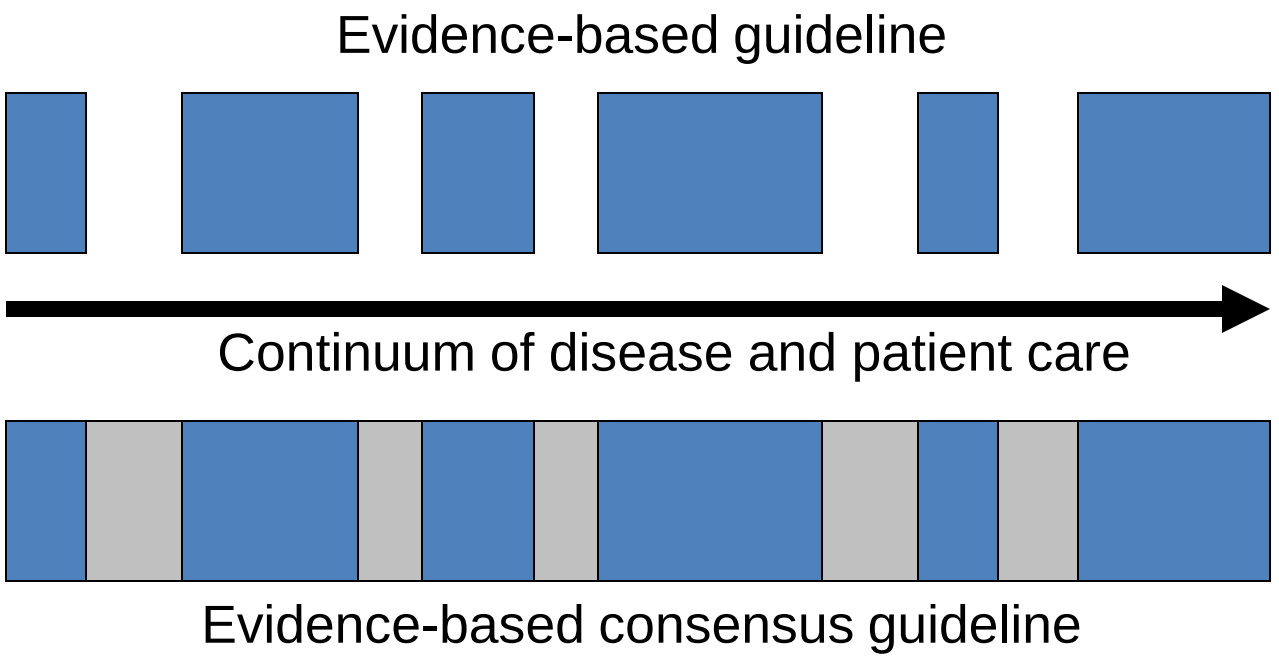
Rationale for Guidelines

- Evidence evaluated and recommendations made by experts
- Objective, explicit decision making process
- Minimize variation in care
- Provide standard of care for quality of care assessment
- Payers can assess appropriateness of care
- Educational instruments

Characteristics of high quality guideline development process

- Explicit process
- Evidence-based when possible
- Level of evidence identified for each recommendation
- Multidisciplinary panel
- Expert panelists
- Conflicts of interest managed
- Updated frequently
- Logical and follow though processes of users
- Supporting documentation provided

Evidence-based Consensus Allows Comprehensive Guidelines



High-level evidence exists

Gaps in evidence filled with expert consensus

NCCN Guidelines®

- Standard for clinical care and policy in oncology in United States
- 48 multidisciplinary panels with 25-30 experts per panel
- Estimated 21,000+ hours volunteered by Guidelines Panel Members in 2013
- 59 NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) with 163 algorithms updated continuously
- Widely available free of charge on the Internet
- Basis for insurance coverage policy and quality evaluation

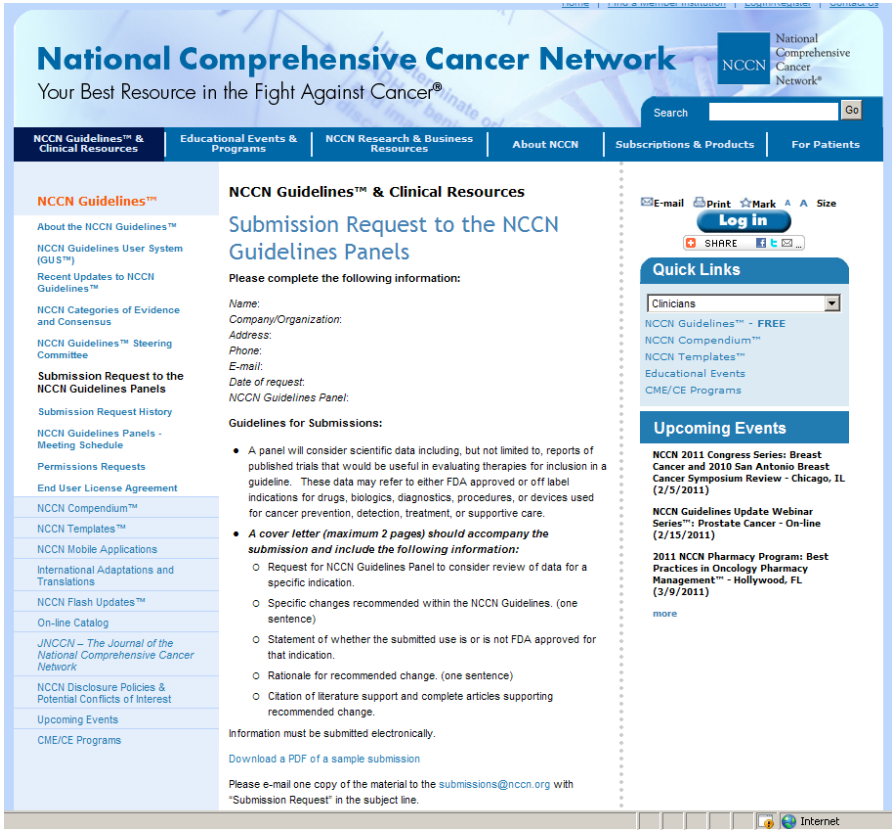
NCCN Process: Identification of Discussion Items

- Staff literature search for clinical trials reports
- NCCN institutional review
- Panel member review
- Patient advocacy review
- Pharmaceutical industry and payor requests
- Community oncology requests
- Individual recommendations

Panel Member Responsibilities

- Manage institutional reviews of guidelines
- Prepare for and participate in panel meetings
- Review draft guidelines
- Participate in development of derivative products
- Respond to availability polls
- Complete COI disclosures semi-annually
  - Clinical trials participation disclosed but not counted against $$ thresholds
  - Limits for panel participation: $20,000 from one source, $50,000 aggregate from all sources
  - Panel member, spouse, domestic partner, dependents

Submission of Data to Panels



- Institutional Review: Each panel member is responsible for submitting guideline to the disease team at his/her institution
- Submissions from community sites, industry, payers, and the advocacy community:
  - Data submitted to the NCCN (not to individual panel members)
  - Quality of data very important
- Panels review and interpret the data using their expert judgment

NCCN Guidelines®

Annual Meeting and Update Process

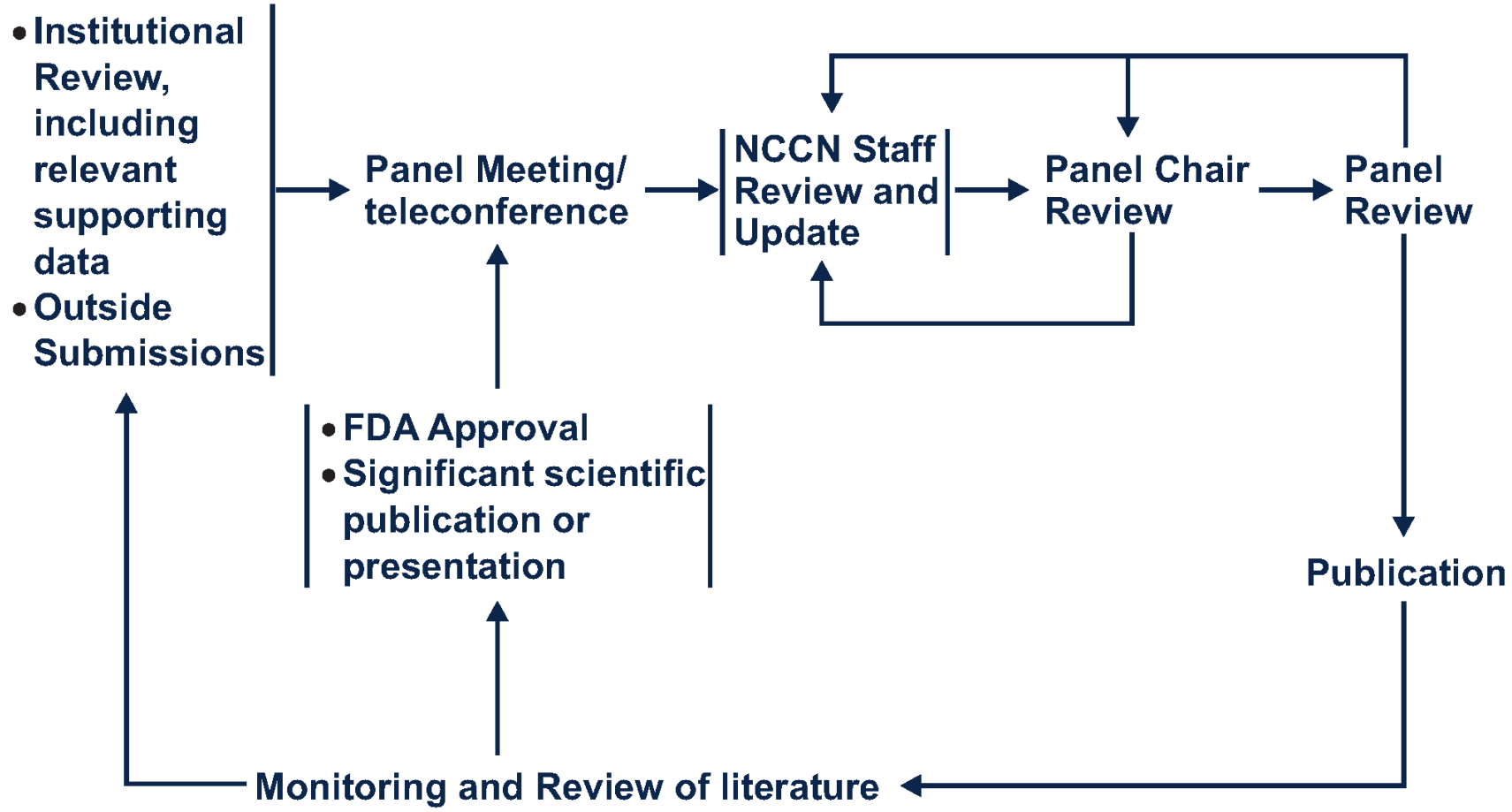
PRE-MEETING
- Identification of new issues
  - Panel chair and members, institutional review, staff, industry, others
- Assignment of issue to specific panelist(s) in advance
- Agenda is circulated in advance of the meeting

AT MEETING
- Disclosure of conflicts of interest
- Formal presentation of evidence by panelist(s) and recommendation
- Discussion by panel
- Decision regarding potential modification

POST-MEETING
- Generation of modified Guideline and supporting documentation
- Dissemination of Guideline

NCCN National Comprehensive Cancer Network®

Guidelines Update Process



Concurrent development and production of Discussion, Compendium and Chemotherapy Order Templates

Critical Analysis of Data

- NCCN Categories of Evidence
  - 1, 2A, 2B, 3
- Quality of evidence
  - Meta analysis/systematic review, RCTs, nonRCTs, clinical experience
- Extent of evidence
  - Extensive, less extensive, little, clinical experience
- Consistency of evidence
  - Highly consistent, single trial, variable data

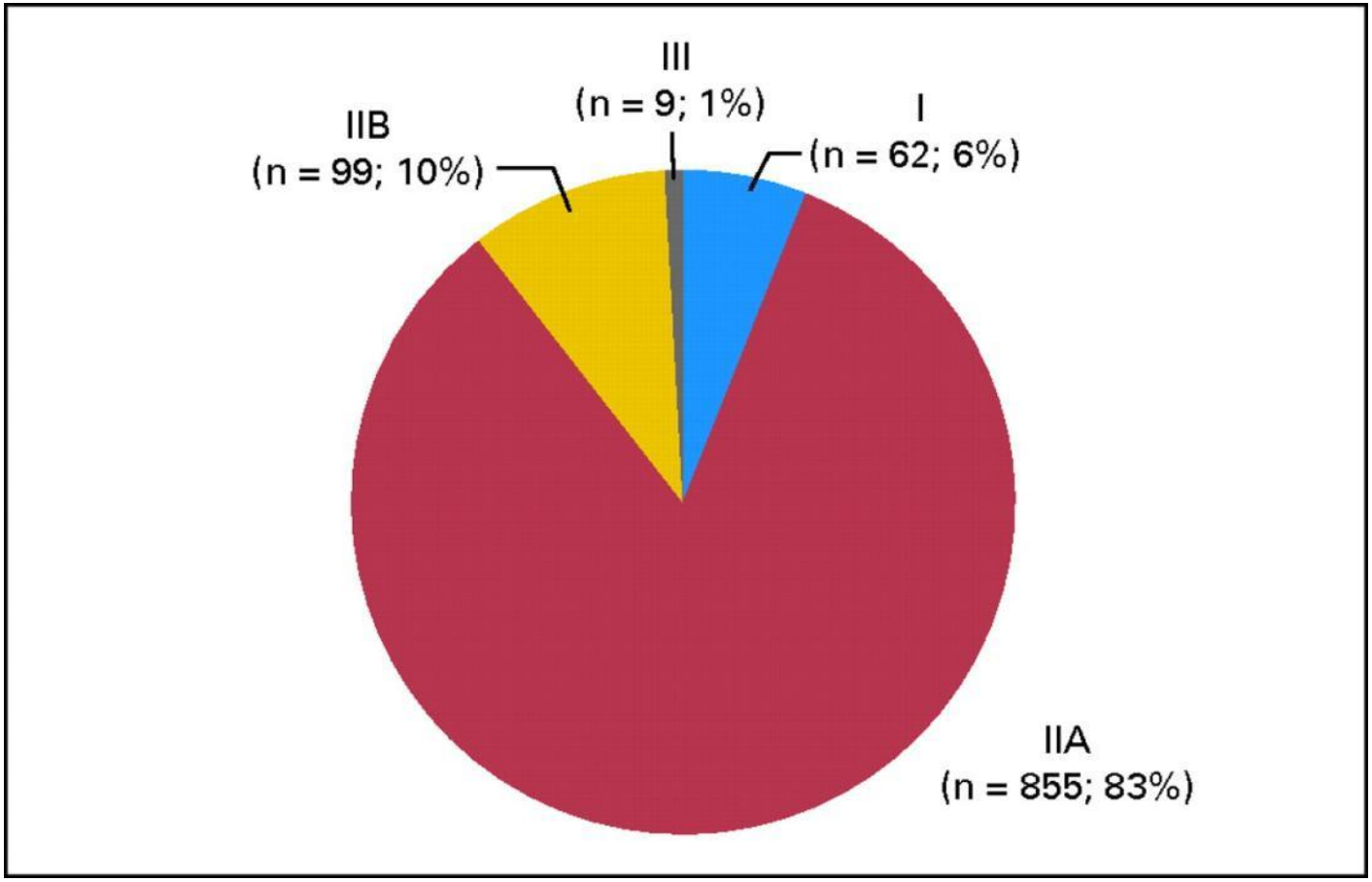
NCCN Guidelines®

Categories of Evidence and Consensus

- **Category 1:** Based upon high-level evidence, there is uniform NCCN consensus (≥85%) that the intervention is appropriate.
- **Category 2A:** Based upon lower-level evidence, there is uniform NCCN consensus (≥85%) that the intervention is appropriate.
- **Category 2B:** Based upon lower-level evidence, there is NCCN consensus (50-85%) that the intervention is appropriate.
- **Category 3:** Based upon any level of evidence, there is major NCCN disagreement (at least 3 institutions on each side) that the intervention is appropriate.

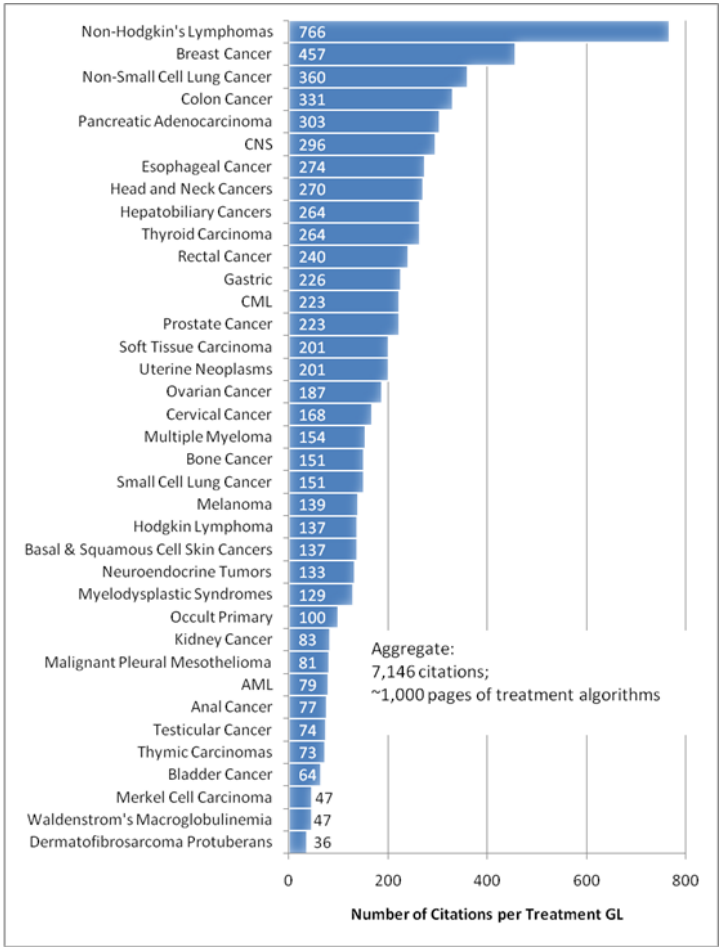
All recommendations are category 2A unless otherwise noted.

Recommendations by Category



Poonacha T K , Go R S JCO 2011;29:186-191

Citations Across Guidelines
Preliminary Data



In general:

- More references:
  - Large complicated guidelines
  - Large number of patient cohorts
  - High priority cancers
- Fewer references
  - Lower incidence
  - Few innovations
  - Fewer effective interventions

NCCN Guidelines®

Minimization of Bias

- Large number of panel members
- Multidisciplinary (e.g., med onc, radiation, surgery, nursing, others) membership
- Geographic diversity
- Different philosophical views represented
- Institutional review
- External review and input: submissions, conferences/symposia, international
- Formal declaration of potential conflicts: verbal/written

NCCN Guidelines®

NCCN Clinical Practice Guidelines Multidisciplinary Panels

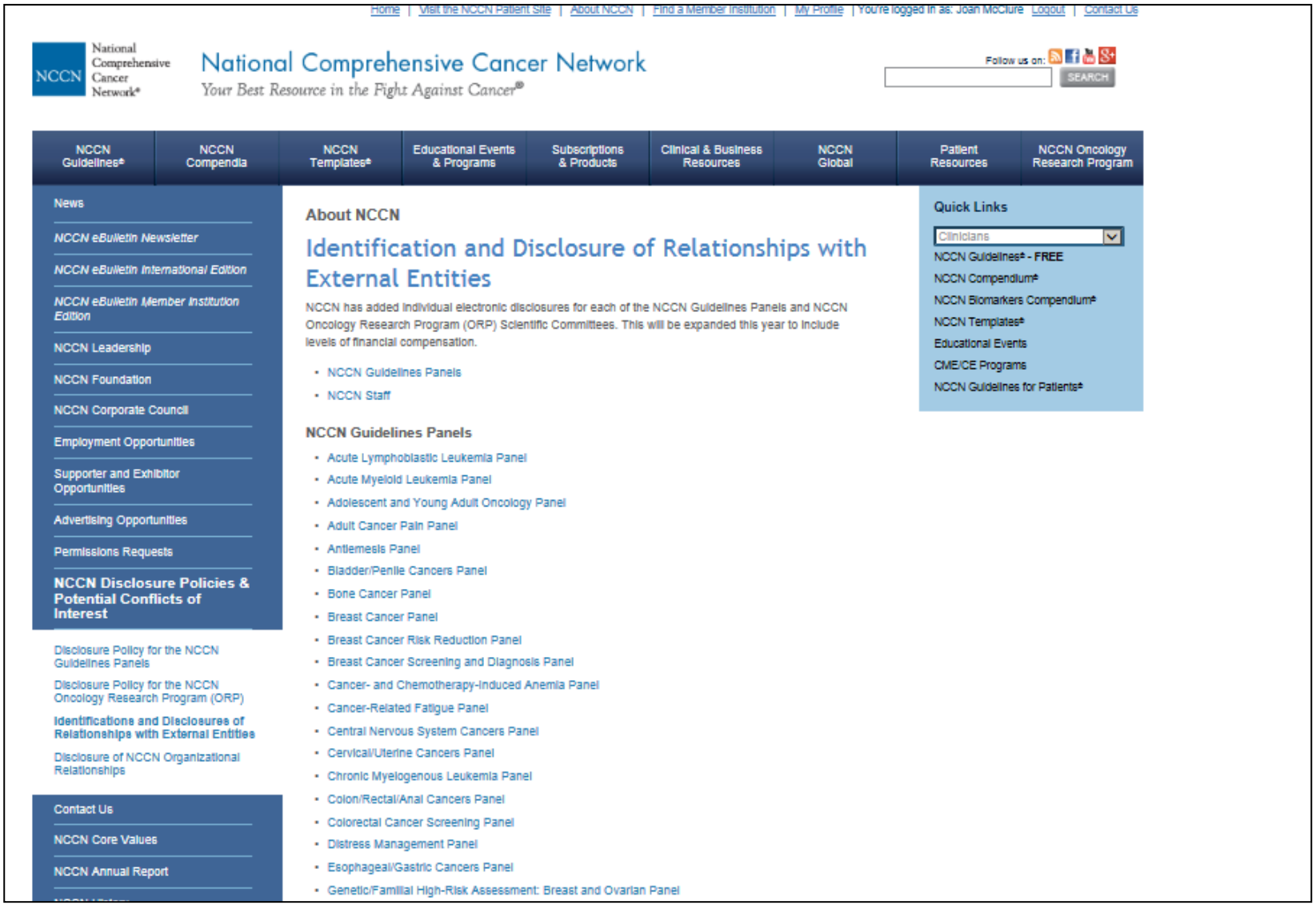
- Medical oncology
- Surgery/Surgical oncology
- Radiation oncology
- Hematology/Hematology oncology
- Bone Marrow Transplantation
- Urology
- Neurology/neuro-oncology
- Gynecologic oncology
- Otolaryngology
- Orthopedics/orthopedic oncology
- Pathology
- Dermatology
- Internal medicine
- Gastroenterology
- Endocrinology
- Diagnostic Radiology
- Interventional Radiology
- Nursing
- Cancer genetics
- Psychiatry, psychology
- Pulmonary medicine
- Pharmacology/Pharmacy
- Infectious diseases
- Allergy/immunology
- Anesthesiology
- Cardiology
- Geriatric medicine
- Epidemiology
- Patient advocacy
- Palliative, Pain management
- Pastoral care
- Oncology social work

NCCN Guidelines®

Conflict of Interest Disclosure

- No industry or any other interest group funds are used to support panel meetings
- No industry representatives allowed at meetings
- Individual panel members disclose conflicts of interest at semi-annually
- Financial conflicts of interest published for individuals on NCCN.org
- Members are excused from deliberations when degree of conflict warrants
- Members with substantial COI are excluded from panels

Disclosure



Home | Visit the NCCN Patient Site | About NCCN | Find a Member Institution | My Profile | You're logged in as: Joan McClure Logout | Contact Us

National Comprehensive Cancer Network

Your Best Resource in the Fight Against Cancer®

Follow us on: SEARCH

NCCN Guidelines® | NCCN Compendia | NCCN Templates® | Educational Events & Programs | Subscriptions & Products | Clinical & Business Resources | NCCN Global | Patient Resources | NCCN Oncology Research Program

News
NCCN eBulletin Newsletter
NCCN eBulletin International Edition
NCCN eBulletin Member Institution Edition
NCCN Leadership
NCCN Foundation
NCCN Corporate Council
Employment Opportunities
Supporter and Exhibitor Opportunities
Advertising Opportunities
Permissions Requests
NCCN Disclosure Policies & Potential Conflicts of Interest

Disclosure Policy for the NCCN Guidelines Panels
Disclosure Policy for the NCCN Oncology Research Program (ORP)
Identifications and Disclosures of Relationships with External Entities
Disclosure of NCCN Organizational Relationships

Contact Us
NCCN Core Values
NCCN Annual Report

About NCCN

Identification and Disclosure of Relationships with External Entities

NCCN has added individual electronic disclosures for each of the NCCN Guidelines Panels and NCCN Oncology Research Program (ORP) Scientific Committees. This will be expanded this year to include levels of financial compensation.

- NCCN Guidelines Panels
- NCCN Staff

NCCN Guidelines Panels

- Acute Lymphoblastic Leukemia Panel
- Acute Myeloid Leukemia Panel
- Adolescent and Young Adult Oncology Panel
- Adult Cancer Pain Panel
- Antiemesis Panel
- Bladder/Penile Cancers Panel
- Bone Cancer Panel
- Breast Cancer Panel
- Breast Cancer Risk Reduction Panel
- Breast Cancer Screening and Diagnosis Panel
- Cancer- and Chemotherapy-Induced Anemia Panel
- Cancer-Related Fatigue Panel
- Central Nervous System Cancers Panel
- Cervical/Uterine Cancers Panel
- Chronic Myelogenous Leukemia Panel
- Colon/Rectal/Anal Cancers Panel
- Colorectal Cancer Screening Panel
- Distress Management Panel
- Esophageal/Gastric Cancers Panel
- Genetic/Familial High-Risk Assessment: Breast and Ovarian Panel

Quick Links

Clinicians
NCCN Guidelines® - FREE
NCCN Compendium®
NCCN Biomarkers Compendium®
NCCN Templates®
Educational Events
CME/CE Programs
NCCN Guidelines for Patients®

Panel Member Disclosures

National Comprehensive Cancer Network

Your Best Resource in the Fight Against Cancer®

Follow us on: SEARCH

NCCN Guidelines® | NCCN Compendia | NCCN Templates® | Educational Events & Programs | Subscriptions & Products | Clinical & Business Resources | NCCN Global | Patient Resources | NCCN Oncology Research Program

News
NCCN eBulletin Newsletter
NCCN eBulletin International Edition
NCCN eBulletin Member Institution Edition
NCCN Leadership
NCCN Foundation
NCCN Corporate Council
Employment Opportunities
Supporter and Exhibitor Opportunities
Advertising Opportunities
Permissions Requests
NCCN Disclosure Policies & Potential Conflicts of Interest

Disclosure Policy for the NCCN Guidelines Panels
Disclosure Policy for the NCCN Oncology Research Program (ORP)
Identifications and Disclosures of Relationships with External Entities
Disclosure of NCCN Organizational Relationships

Contact Us
NCCN Core Values
NCCN Annual Report

About NCCN

Cervical/Uterine Cancers Panel - Disclosures as of 5/28/2014

View NCCN Management Team Disclosures | View NCCN Guidelines Staff Disclosures | View NCCN ORP Staff Disclosures

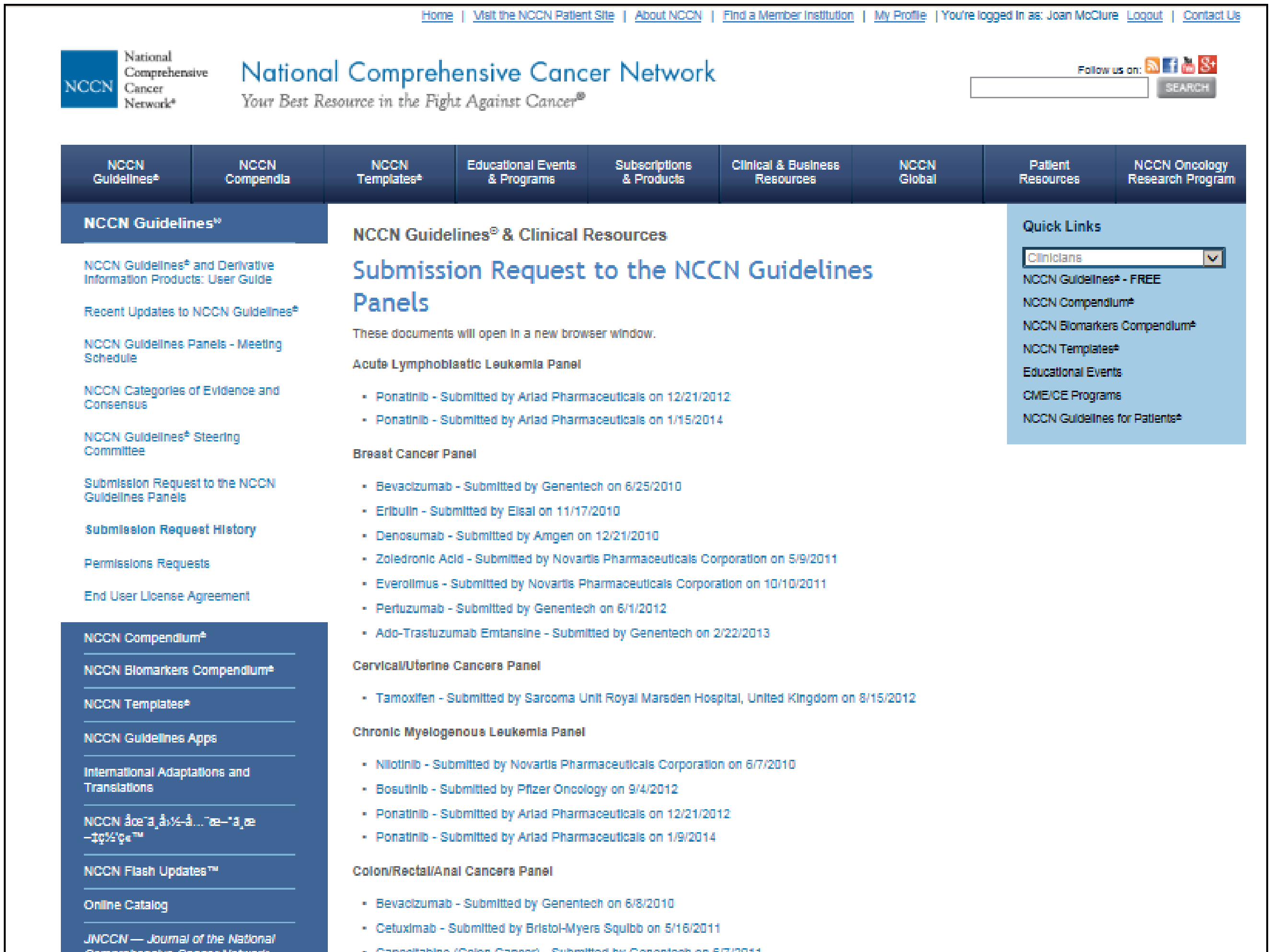
Panel Member	Clinical Research Support/Data Safety Monitoring Board	Advisory Boards, Speakers Bureau, Expert Witness, or Consultant	Patent, Equity, or Royalty	Other	Date Completed
Nadeem R. Abu-Rustum, MD	None	None	None	None	4/17/2014
Sachin M. Apte, MD, MS	None	None	None	None	4/18/2014
Susana M. Campos, MD, MPH, MS	None	Boehringer Ingelheim GmbH	None	None	12/2/2013
Kathleen R. Cho, MD	None	None	None	None	5/16/2013
Christina Chu, MD	Azaya; Cervical Cancer Free America; Healthbanks; Inovio; Prima Biomed; Transdiciplinary Research on Energetics and Cancer Initiative	None	None	None	4/3/2014
David Cohn, MD	None	None	None	None	8/16/2013
	AstraZeneca Pharmaceuticals LP; Novartis Pharmaceuticals	None	None	None	5/5/2014

NCCN Transparency Procedures

- Requests for changes in recommendations for drugs and biologics to a guideline are available to the public for a period of not less than 5 years
- A listing of all evidence reviewed or considered
- A listing of all individuals who have substantively participated in the review
- Minutes and voting records of meetings for the review and disposition
- Direct or indirect financial relationships that exist between individuals or the spouse or minor child of individuals who have substantively participated

NCCN Guidelines®

Transparency Documents



Home | Visit the NCCN Patient Site | About NCCN | Find a Member Institution | My Profile | You're logged in as: Joan McClure Logout | Contact Us

NCCN National Comprehensive Cancer Network®

National Comprehensive Cancer Network
Your Best Resource in the Fight Against Cancer®

Follow us on:
SEARCH

NCCN Guidelines® | NCCN Compendia | NCCN Templates® | Educational Events & Programs | Subscriptions & Products | Clinical & Business Resources | NCCN Global | Patient Resources | NCCN Oncology Research Program

NCCN Guidelines®

- NCCN Guidelines® and Derivative Information Products: User Guide
- Recent Updates to NCCN Guidelines®
- NCCN Guidelines Panels - Meeting Schedule
- NCCN Categories of Evidence and Consensus
- NCCN Guidelines® Steering Committee
- Submission Request to the NCCN Guidelines Panels
- **Submission Request History**
- Permissions Requests
- End User License Agreement

- NCCN Compendium®
- NCCN Biomarkers Compendium®
- NCCN Templates®
- NCCN Guidelines Apps
- International Adaptations and Translations
- NCCN åœ¨ä¸å…¨...¨æ—¨ä¸æ –‡ç½'ç«™
- NCCN Flash Updates™
- Online Catalog
- *JNCCN — Journal of the National Comprehensive Cancer Network*

NCCN Guidelines® & Clinical Resources

Submission Request to the NCCN Guidelines Panels

These documents will open in a new browser window.

Acute Lymphoblastic Leukemia Panel

- Ponatinib - Submitted by Ariad Pharmaceuticals on 12/21/2012
- Ponatinib - Submitted by Ariad Pharmaceuticals on 1/15/2014

Breast Cancer Panel

- Bevacizumab - Submitted by Genentech on 6/25/2010
- Eribulin - Submitted by Eisai on 11/17/2010
- Denosumab - Submitted by Amgen on 12/21/2010
- Zoledronic Acid - Submitted by Novartis Pharmaceuticals Corporation on 5/9/2011
- Everolimus - Submitted by Novartis Pharmaceuticals Corporation on 10/10/2011
- Pertuzumab - Submitted by Genentech on 6/1/2012
- Ado-Trastuzumab Emtansine - Submitted by Genentech on 2/22/2013

Cervical/Uterine Cancers Panel

- Tamoxifen - Submitted by Sarcoma Unit Royal Marsden Hospital, United Kingdom on 8/15/2012

Chronic Myelogenous Leukemia Panel

- Nilotinib - Submitted by Novartis Pharmaceuticals Corporation on 6/7/2010
- Bosutinib - Submitted by Pfizer Oncology on 9/4/2012
- Ponatinib - Submitted by Ariad Pharmaceuticals on 12/21/2012
- Ponatinib - Submitted by Ariad Pharmaceuticals on 1/9/2014

Colon/Rectal/Anal Cancers Panel

- Bevacizumab - Submitted by Genentech on 6/8/2010
- Cetuximab - Submitted by Bristol-Myers Squibb on 5/16/2011
- Capecitabine (Colon Cancer) - Submitted by Genentech on 6/7/2011

Quick Links

Clinicians

- NCCN Guidelines® - FREE
- NCCN Compendium®
- NCCN Biomarkers Compendium®
- NCCN Templates®
- Educational Events
- CME/CE Programs
- NCCN Guidelines for Patients®

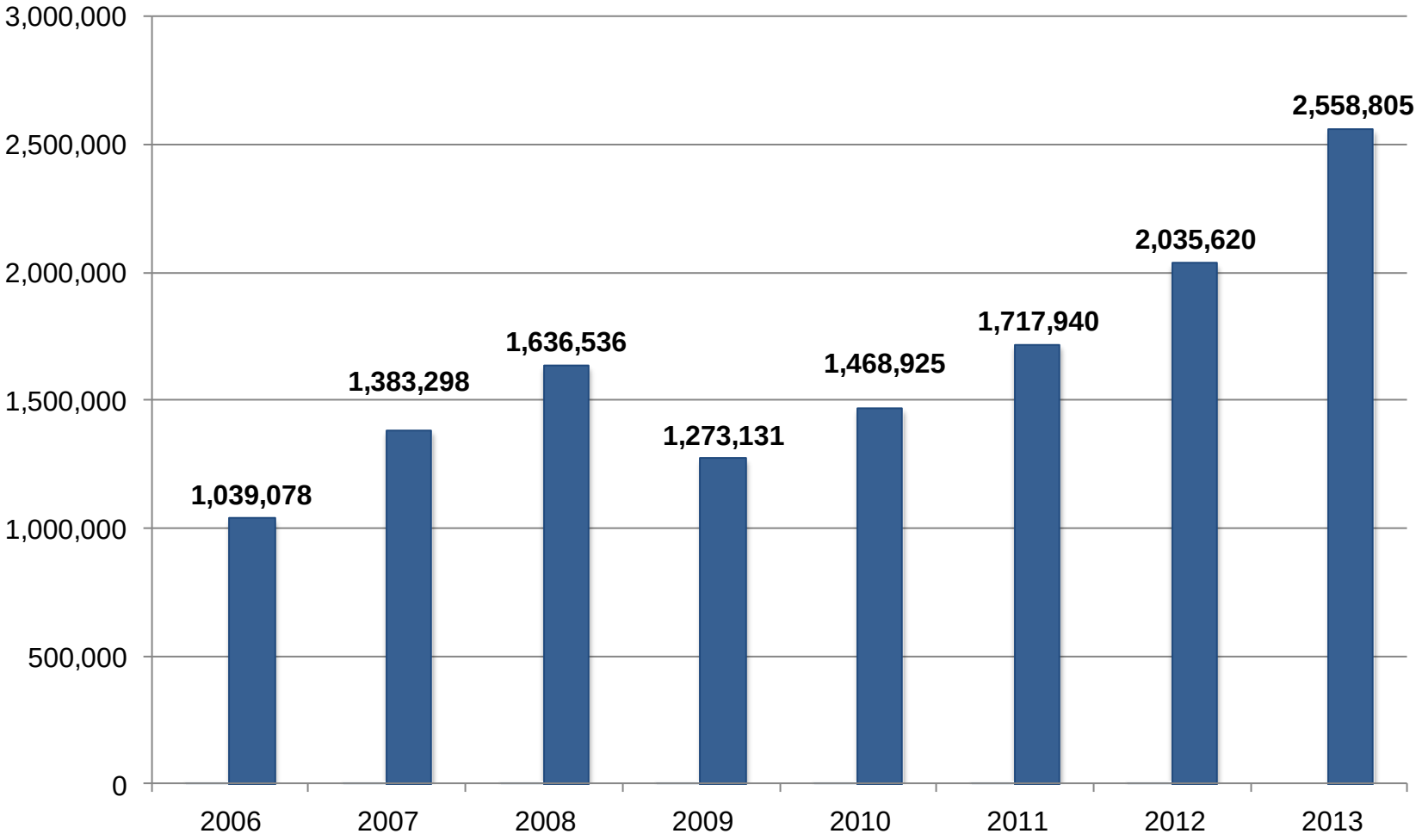
NCCN Guidelines®

Dissemination of Guidelines

- Algorithms always published with supporting documentation (manuscript)
- Available free of charge via internet (www.nccn.org)
- Released on flash drives
- Published in JNCCN periodically
- Have been translated into multiple languages, including Japanese, Chinese, Spanish
- Selectively available in patient-oriented versions.

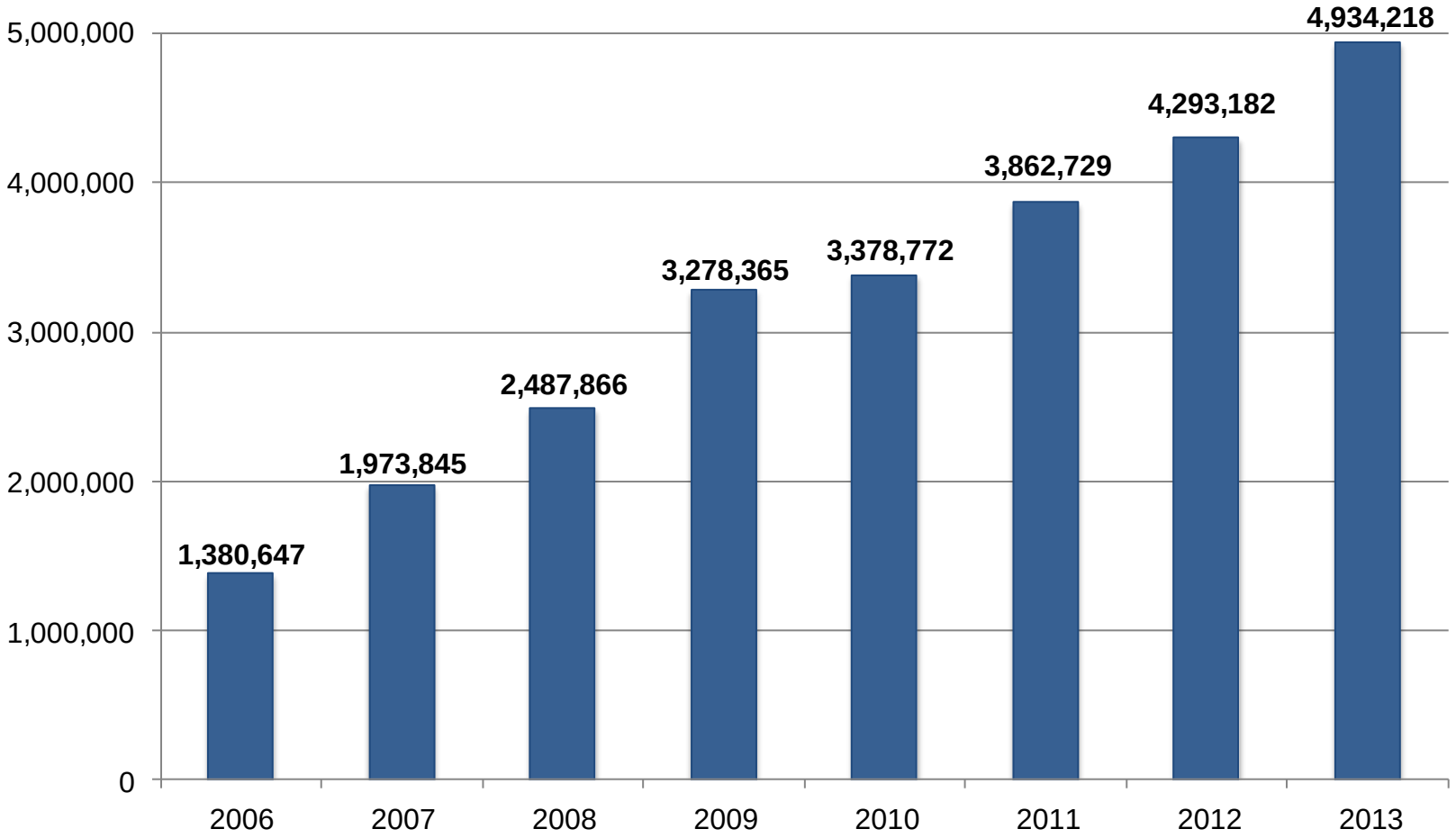
NCCN.org

Unique Visitors to NCCN.org



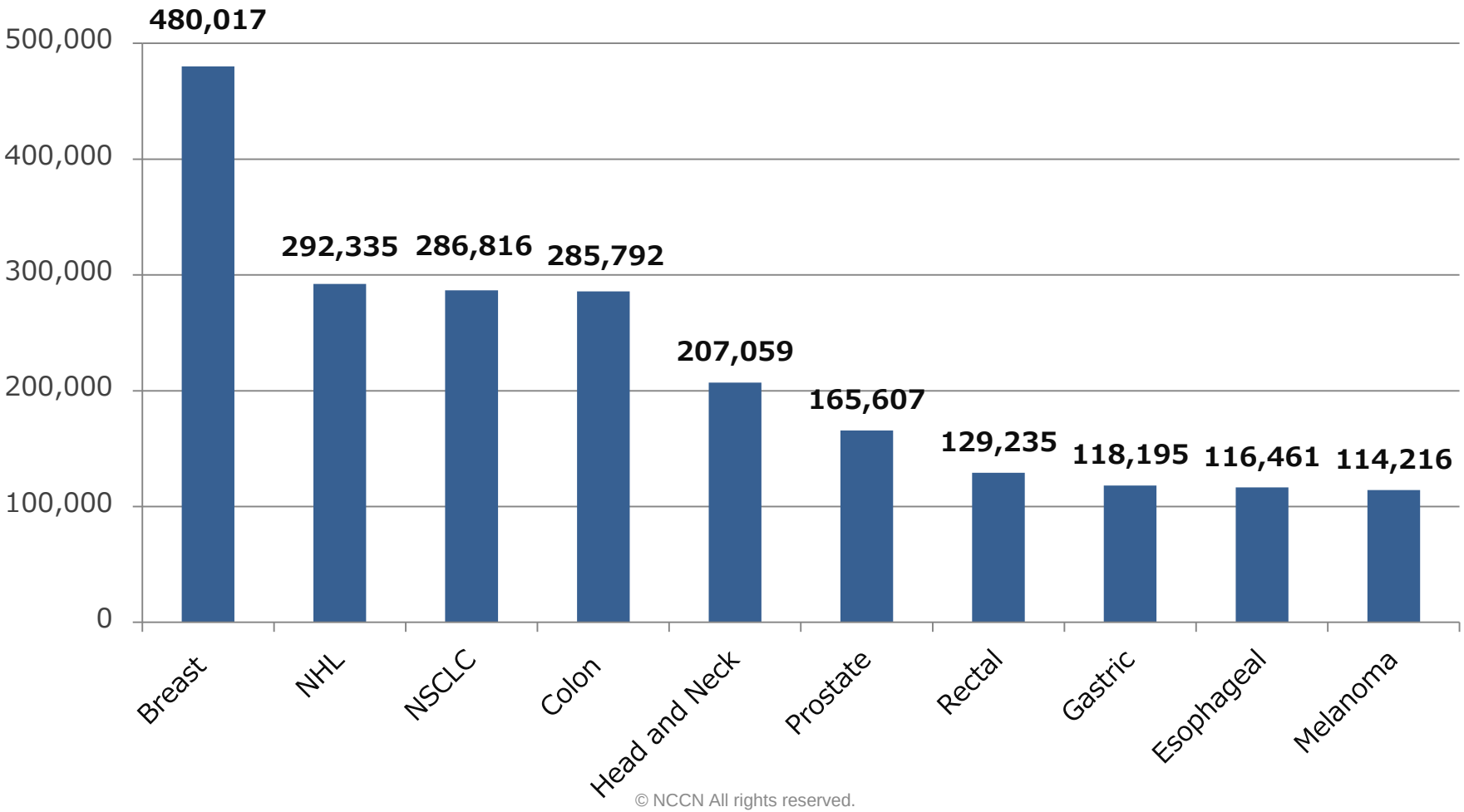
Guideline Downloads

More Than 25 Million Downloads Since 2006



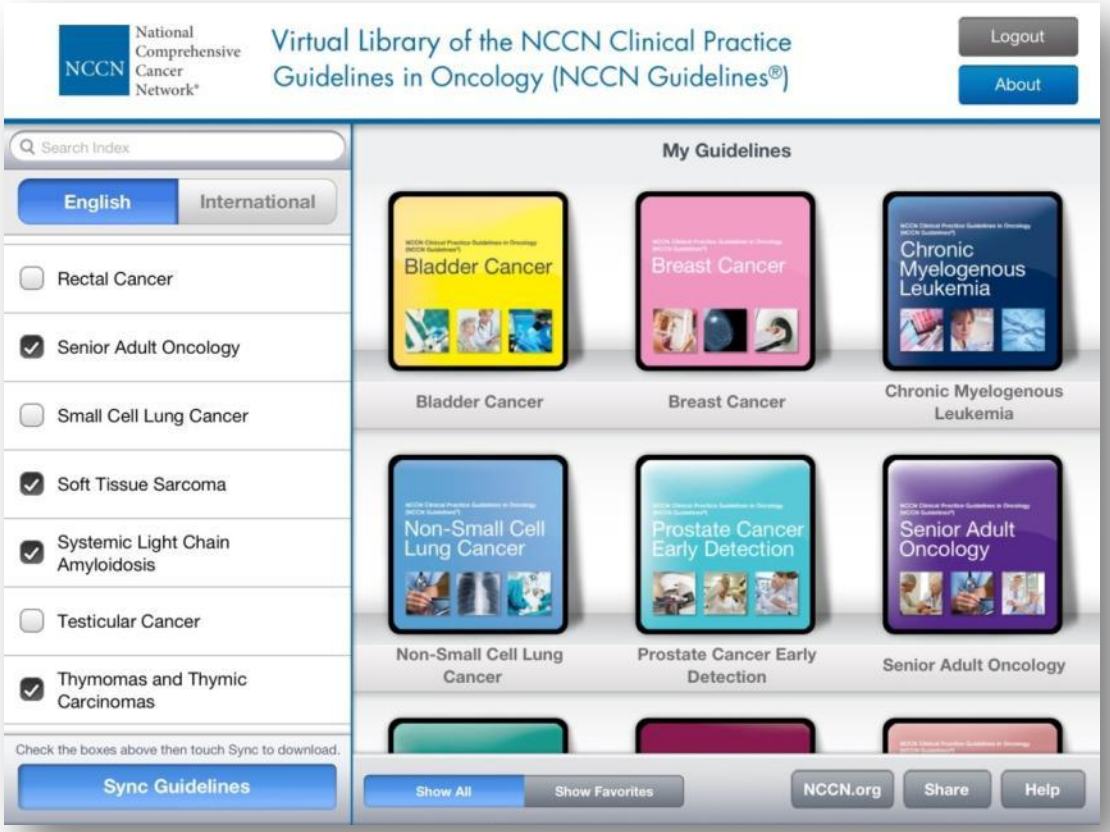
NCCN.org

2013 Top 10 Guideline Views



Virtual Library of NCCN Guidelines®

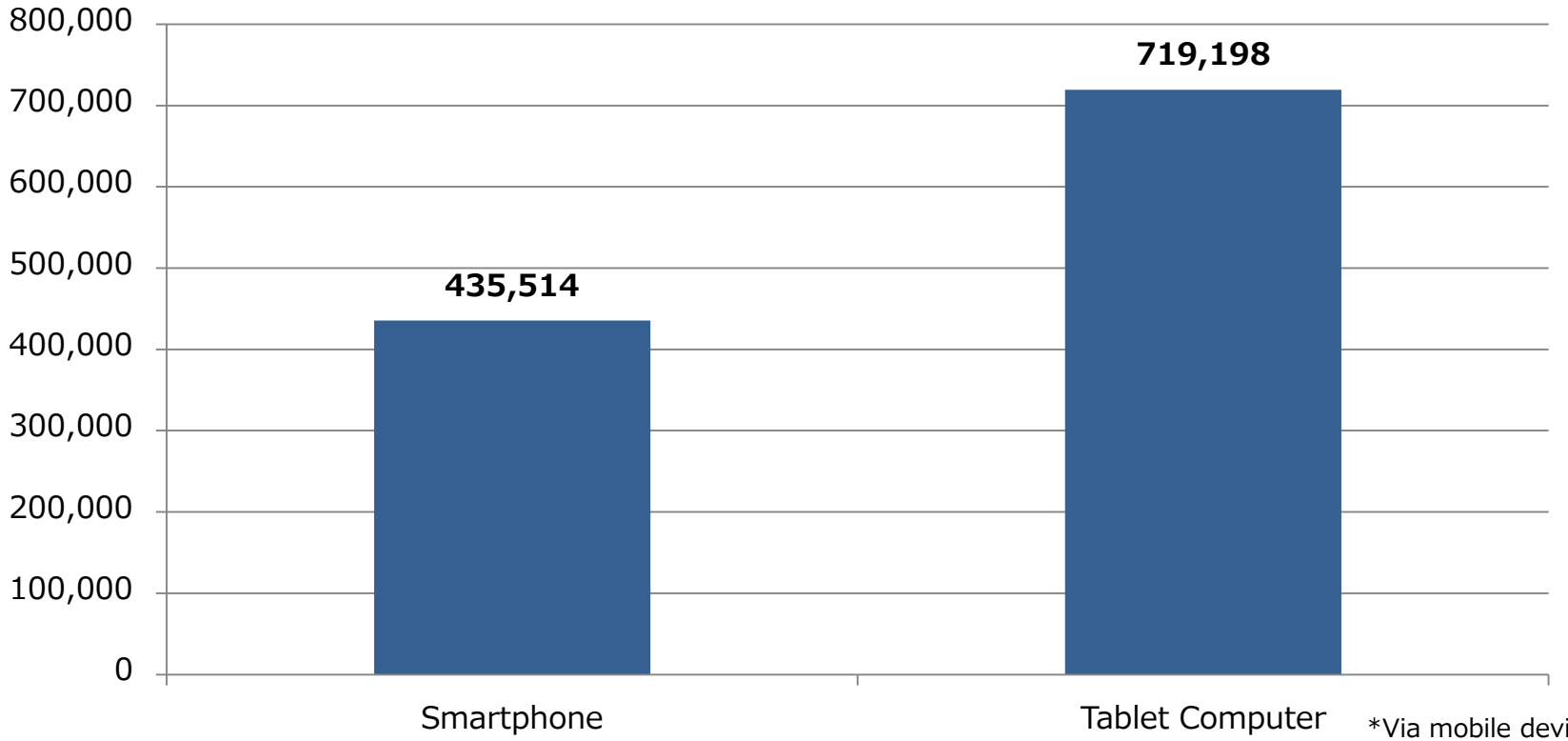
Access the Complete Library, including International Editions and Translations



Virtual Library of NCCN Guidelines®

On December 13, 2013, NCCN launched the Virtual Library of NCCN Guidelines® Free App formatted for iPhone and Android Smartphone in addition to the already existing tablet applications, which was launched in September, 2012

More Than One Million Guideline Downloads*



*Via mobile device since the App was launched in September, 2012

TOP TEN COUNTRIES: 2013

Country	Web Visits
United States	4,415,769
Spain	147,850
Italy	143,269
Japan	137,239
Brazil	127,248
China	118,877
India	110,317
Canada	109,649
South Korea	90,652
Mexico	78,304

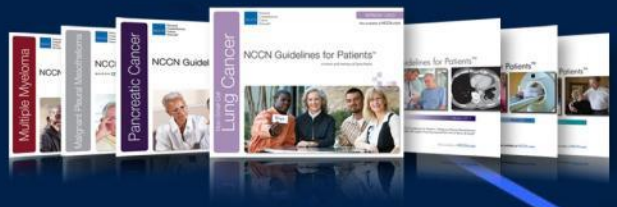
NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)

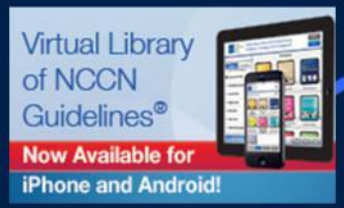
NCCN Chemotherapy Order Templates (NCCN Templates®)

NCCN Drugs & Biologics Compendium (NCCN Compendium®)

NCCN Biomarkers Compendium®

NCCN CONGRESS SERIES 2014





NCCN 19th ANNUAL CONFERENCE: Advancing the Standard of Cancer Care®

evitr · Hines · INTERLINE · United MEDICAL MANAGEMENT · McKESSON · New Century Health · OnHealth · OPTUM · PATIENTS POWER · skyscape · zynxhealth · ACTIVEHEALTH · CareCore NATIONAL · DNAdirect · ELEKTA · EPOCRATES

NCCN Guidelines®

Guideline Value Leveraged for Derivative Products

- NCCN Drugs and Biologics Compendium®
- NCCN Biomarkers Compendium®
- Licensed to multiple IT organizations for use in computer-based systems
- NCCN Guidelines for Patients®

NCCN Compendium®

- Based directly on NCCN Guidelines
- 228 agents used in cancer care
- NCCN Compendium lists both FDA-approved uses and appropriate uses beyond the FDA-approved label
- Recognized as an authoritative reference for oncology coverage policy
- Used by health care professionals to determine coverage of drugs

NCCN Compendium®

National Comprehensive Cancer Network

NCCN | National Comprehensive Cancer Network®

Your Best Resource in the Fight Against Cancer®

Follow us on:

SEARCH

NCCN Guidelines® & Clinical Resources

NCCN Drugs & Biologics Compendium (NCCN Compendium®)

Click here to subscribe to the NCCN Compendium®

Based directly on the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®), the NCCN Drugs & Biologics Compendium (NCCN Compendium®) contains authoritative, scientifically derived information designed to support decision-making about the appropriate use of drugs and biologics in patients with cancer.

The NCCN Compendium® is recognized by public and private insurers alike, including, but not limited to the Centers for Medicare and Medicaid Services (CMS) and UnitedHealthcare as an authoritative reference for oncology coverage policy. Managed care medical directors, pharmacy benefits directors, and other health care professionals also reference the NCCN Compendium when making decisions that impact patient access to appropriate therapy. The uses identified are based upon evaluation of evidence from scientific literature integrated with expert judgment in an evidence-based process. Indicated uses are categorized in a systematic approach that describes the type of evidence available for and the degree of consensus underlying each recommendation. **All recommendations (at all category levels) in the NCCN Compendium constitute appropriate, medically-necessary care.** The NCCN Compendium lists both FDA-approved uses and appropriate uses beyond the FDA-approved label.

Search The Compendium

NCCN Compendium Chapters for Treatment of Cancer by Site

NCCN Compendium Chapters for Detection, Prevention, & Risk Reduction of Cancer

NCCN Compendium Chapters for Supportive Care

Table of Contents

Browse by Generic Name:

A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T, U, V, W, X, Y, Z

Search by Generic name: Search

Quick Links

Clinicians

NCCN Guidelines® - FREE

NCCN Compendium®

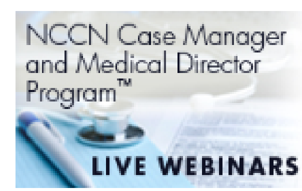
NCCN Biomarkers Compendium®

NCCN Templates®

Educational Events

CME/CE Programs

NCCN Guidelines for Patients®



NCCN Compendium®

NCCN Drugs & Biologics Compendium ®

Ibritumomab tiuxetan

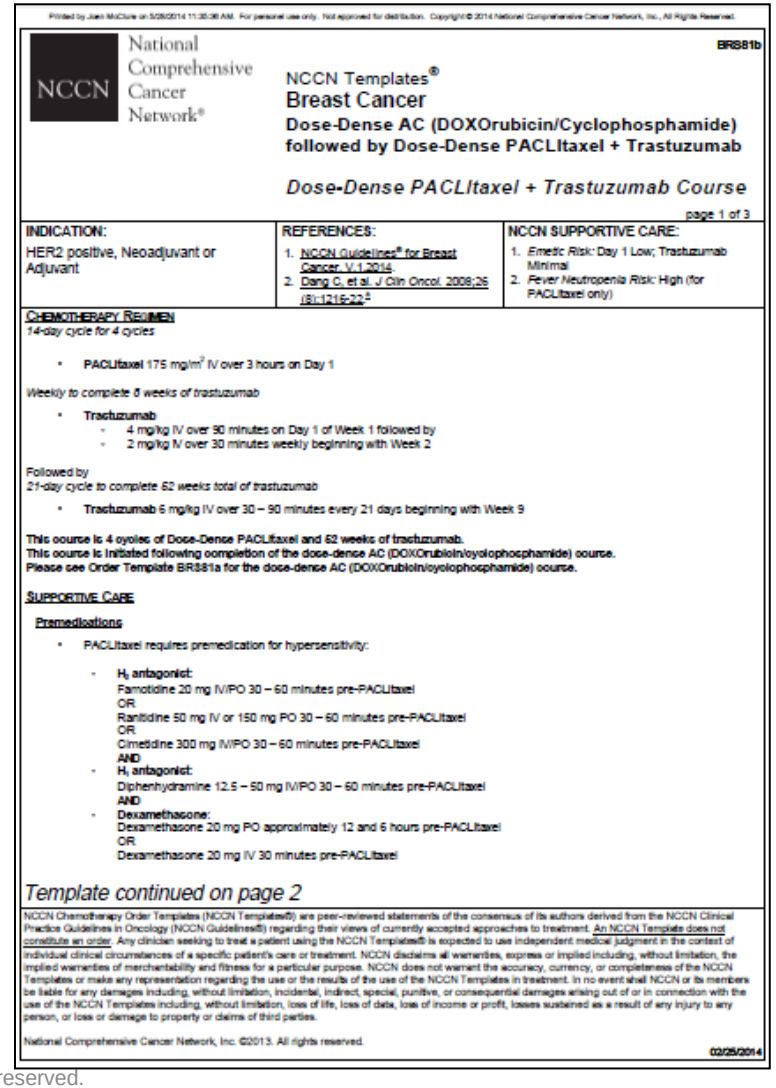
Print | Transparency: Process and Recommendations

National Comprehensive Cancer Network®

NCCN Disease Indication	Agent	Brand Name(s)	Pharmacologic Class	Route(s)	FDA Disease Indication	ICD-9 Code	NCCN Recommended Use	NCCN Category
NHL - Follicular Lymphoma	Ibritumomab tiuxetan	Zevalin®	Antineoplastic radioimmuno-therapeutic anti-CD-20 monoclonal antibody	IV	Ibritumomab tiuxetan is indicated for the treatment of relapsed or refractory low-grade or follicular B-cell non-Hodgkin's lymphoma (NHL). Ibritumomab tiuxetan is indicated for the treatment of previously untreated follicular NHL in patients who achieve a partial or complete response to first-line chemotherapy. Consult the full FDA label with particular attention to boxed warning(s).	202.00-202.08, 200.30-200.38	First-line radioimmunotherapy alone in elderly or infirm patients with the indications for treatment in the setting of comorbidities where tolerability of combination chemotherapy is a concern; following induction chemotherapy or chemoimmunotherapy as first-line consolidation therapy; or as second-line radioimmunotherapy for refractory or progressive disease in patients with the indications for treatment	1 for radioimmunotherapy following induction chemotherapy or chemoimmunotherapy as first-line consolidation therapy and for second-line therapy; 2A for first-line therapy for elderly or infirm patients
NHL - Gastric MALT Lymphoma	Ibritumomab tiuxetan	Zevalin®	Antineoplastic radioimmuno-therapeutic anti-CD-20 monoclonal antibody	IV	Ibritumomab tiuxetan is indicated for the treatment of relapsed or refractory low-grade or follicular B-cell non-Hodgkin's lymphoma (NHL). Ibritumomab tiuxetan is indicated for the treatment of previously untreated follicular NHL in patients who achieve a partial or complete response to first-line chemotherapy. Consult the full FDA label with particular attention to boxed warning(s).	200.30-200.38	First-line radioimmunotherapy alone in elderly or infirm patients with the indications for treatment in the setting of comorbidities where tolerability of combination chemotherapy is a concern; or following induction chemotherapy or chemoimmunotherapy as first-line consolidation therapy for stage III_A-IV disease; or as second-line radioimmunotherapy for recurrent or progressive disease in patients with the indications for treatment	1 for radioimmunotherapy following induction chemotherapy or chemoimmunotherapy as first-line consolidation therapy and for second-line therapy; 2A for first-line therapy for elderly or infirm patients
NHL - Nongastric MALT Lymphoma	Ibritumomab tiuxetan	Zevalin®	Antineoplastic radioimmuno-therapeutic anti-CD-20 monoclonal antibody	IV	Ibritumomab tiuxetan is indicated for the treatment of relapsed or refractory low-grade or follicular B-cell non-Hodgkin's lymphoma (NHL). Ibritumomab tiuxetan is indicated for the treatment of previously untreated follicular NHL in patients who achieve a partial or complete response to first-line chemotherapy. Consult the full FDA label with particular attention to boxed warning(s).	200.30-200.38	First-line radioimmunotherapy alone in elderly or infirm patients with the indications for treatment in the setting of comorbidities where tolerability of combination chemotherapy is a concern; or following induction chemotherapy or chemoimmunotherapy as first-line consolidation therapy for stage III-IV disease; or second-line radioimmunotherapy for recurrent stage I-II disease or for progressive disease in patients with the indications for treatment	1 for radioimmunotherapy following chemotherapy or chemoimmunotherapy as first-line consolidation therapy and for second-line therapy; 2A for first-line therapy for elderly or infirm patients
NHL - Primary Cutaneous B-Cell Lymphoma	Ibritumomab tiuxetan	Zevalin®	Antineoplastic radioimmuno-therapeutic anti-CD-20 monoclonal antibody	IV	Ibritumomab tiuxetan is indicated for the treatment of relapsed or refractory low-grade or follicular B-cell non-Hodgkin's lymphoma (NHL). Ibritumomab tiuxetan is indicated for the treatment of previously untreated follicular NHL in patients who achieve a partial or complete response to first-line chemotherapy. Consult the full FDA label with particular attention to boxed warning(s).	200.80-200.88, 202.80-202.88, V10.79	Radioimmunotherapy alone, including in elderly or infirm patients with the indications for treatment in the setting of comorbidities where tolerability of combination chemotherapy is a concern, or following induction chemotherapy or chemoimmunotherapy as first-line consolidation therapy for refractory generalized cutaneous or newly diagnosed generalized extracutaneous primary cutaneous marginal zone or follicle center lymphoma or as second-line radioimmunotherapy for refractory generalized cutaneous disease or relapsed generalized extracutaneous disease in patients with the indications for treatment	1 for radioimmunotherapy following induction chemotherapy or chemoimmunotherapy as consolidation therapy and for second-line therapy; 2A for first-line therapy for elderly or infirm patients; 3 for first-line therapy
NHL - Splenic Marginal Zone Lymphoma	Ibritumomab tiuxetan	Zevalin®	Antineoplastic radioimmuno-therapeutic anti-CD-20 monoclonal antibody	IV	Ibritumomab tiuxetan is indicated for the treatment of relapsed or refractory low-grade or follicular B-cell non-Hodgkin's lymphoma (NHL). Ibritumomab tiuxetan is indicated for the treatment of previously untreated follicular NHL in patients who achieve a partial or complete response to first-line chemotherapy. Consult the full FDA label with particular attention to boxed warning(s).	200.30-200.38, V10.79	For progressive disease following initial treatment for splenomegaly in patients with the indications for treatment as • first-line radioimmunotherapy alone in elderly or infirm patients with the indications for treatment in the setting of comorbidities where tolerability of combination chemotherapy is a concern or following induction chemotherapy or chemoimmunotherapy as first-line consolidation therapy	1 for radioimmunotherapy following chemotherapy for first-line consolidation therapy and for second-line therapy; 2A for first-line therapy for elderly or

NCCN Templates®

- Helps clinicians administer regimens and agents in the NCCN Guidelines and Compendium safely and effectively
- References NCCN Guidelines and relevant studies
- Includes emetic risk and FN risk from NCCN Guidelines, monitoring and cautions etc
- NCCN currently has 1041 posted templates
- NCCN is developing electronic-facing interface



BRS81b

National Comprehensive Cancer Network®

NCCN Templates®

Breast Cancer

Dose-Dense AC (DOXOrubicin/Cyclophosphamide) followed by Dose-Dense PACLItaxel + Trastuzumab

Dose-Dense PACLItaxel + Trastuzumab Course

INDICATION:
HER2 positive, Neoadjuvant or Adjuvant

REFERENCES:
1. NCCN Guidelines® for Breast Cancer. V.1.2014.
2. Dang C, et al. J Clin Oncol. 2006;26 (8):1216-22.[a]

NCCN SUPPORTIVE CARE:
1. *Emetic Risk:* Day 1 Low; Trastuzumab Minimal
2. *Fever Neutropenia Risk:* High (for PACLItaxel only)

CHEMOTHERAPY REGIMEN
14-day cycle for 4 cycles

- **PACLItaxel** 175 mg/m^2 IV over 3 hours on Day 1

Weekly to complete 6 weeks of trastuzumab

- **Trastuzumab**
  - 4 mg/kg IV over 90 minutes on Day 1 of Week 1 followed by
  - 2 mg/kg IV over 30 minutes weekly beginning with Week 2

Followed by
21-day cycle to complete 52 weeks total of trastuzumab

- **Trastuzumab** 6 mg/kg IV over 30 – 90 minutes every 21 days beginning with Week 9

This course is 4 cycles of Dose-Dense PACLItaxel and 52 weeks of trastuzumab.
This course is initiated following completion of the dose-dense AC (DOXOrubicin/cyclophosphamide) course.
Please see Order Template BRS81a for the dose-dense AC (DOXOrubicin/cyclophosphamide) course.

SUPPORTIVE CARE

Premedications

- PACLItaxel requires premedication for hypersensitivity:
  - **H_1 antagonist:**
    Famotidine 20 mg IV/PO 30 – 60 minutes pre-PACLItaxel
    OR
    Ranitidine 50 mg IV or 150 mg PO 30 – 60 minutes pre-PACLItaxel
    OR
    Cimetidine 300 mg IV/PO 30 – 60 minutes pre-PACLItaxel
    AND
  - **H_1 antagonist:**
    Diphenhydramine 12.5 – 50 mg IV/PO 30 – 60 minutes pre-PACLItaxel
    AND
  - **Dexamethasone:**
    Dexamethasone 20 mg PO approximately 12 and 6 hours pre-PACLItaxel
    OR
    Dexamethasone 20 mg IV 30 minutes pre-PACLItaxel

Template continued on page 2

02/25/2014

NCCN Biomarkers Compendium™

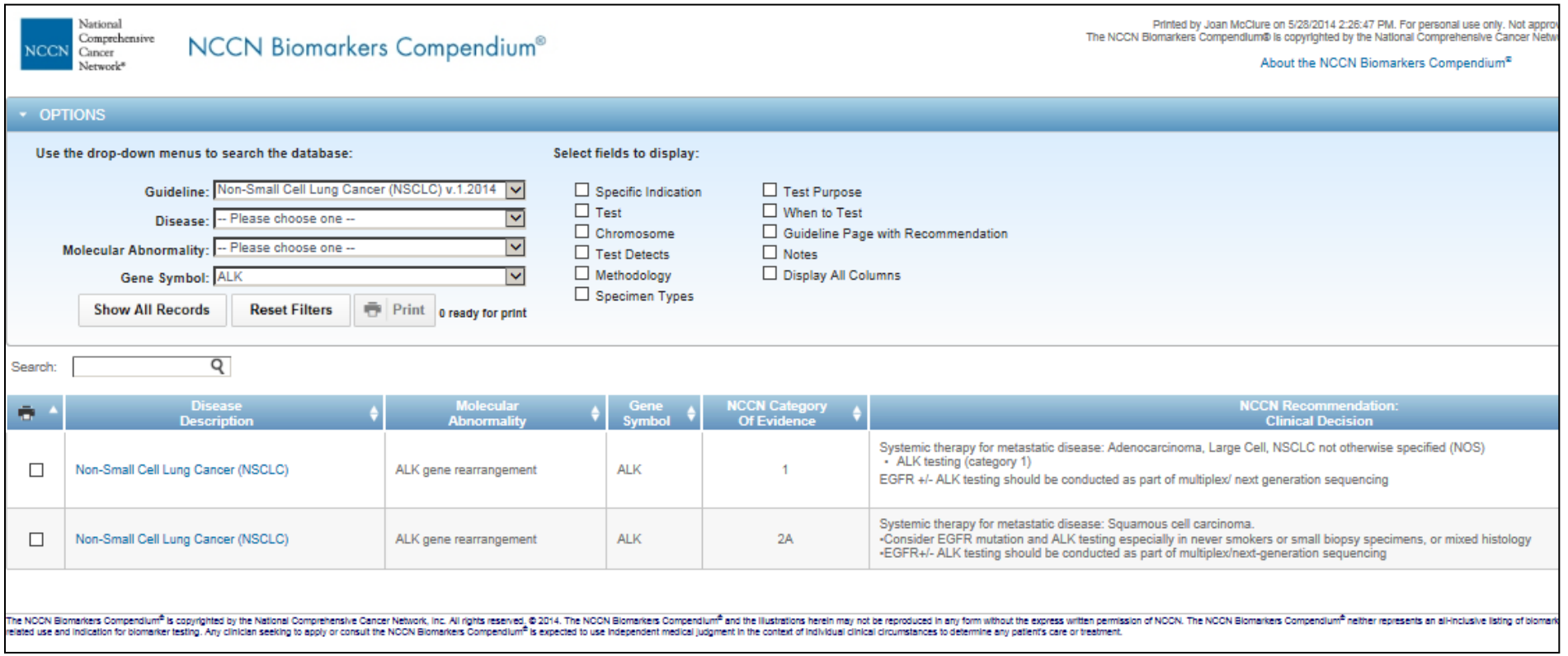
Launched December 1, 2012

- Goal: To ensure access to appropriate testing as recommended by NCCN Guidelines
- Identify the utility of a biomarker to screen, diagnose, monitor, or provide predictive or prognostic information
- Use broad definition
- Identify biomarkers that affect treatment decisions and can divide patients into clinically relevant subgroups
- Consider the biologic activity not the specific test
- Widespread availability of reliable testing

NCCN Biomarkers Compendium™

Test Detects	Number of Recommendations	Number of unique entities (gene symbols, rearrangements, translocations, etc
Protein/Protein Expression (includes flow/IHC)	558	112
Translocation	105	64
Mutation	87	36
Chromosome deletion, abnormality, trisomy, inversion, complex alteration, etc.[1]	50	
Gene rearrangements	40	10

Search



National Comprehensive Cancer Network

NCCN Biomarkers Compendium®

About the NCCN Biomarkers Compendium®

OPTIONS

Use the drop-down menus to search the database:

Guideline: Non-Small Cell Lung Cancer (NSCLC) v.1.2014
Disease: -- Please choose one --
Molecular Abnormality: -- Please choose one --
Gene Symbol: ALK

Show All Records | Reset Filters | Print | 0 ready for print

Select fields to display:

- Specific Indication
- Test
- Chromosome
- Test Detects
- Methodology
- Specimen Types
- Test Purpose
- When to Test
- Guideline Page with Recommendation
- Notes
- Display All Columns

Search:

Disease Description	Molecular Abnormality	Gene Symbol	NCCN Category Of Evidence	NCCN Recommendation: Clinical Decision
Non-Small Cell Lung Cancer (NSCLC)	ALK gene rearrangement	ALK	1	Systemic therapy for metastatic disease: Adenocarcinoma, Large Cell, NSCLC not otherwise specified (NOS) • ALK testing (category 1) EGFR +/- ALK testing should be conducted as part of multiplex/ next generation sequencing
Non-Small Cell Lung Cancer (NSCLC)	ALK gene rearrangement	ALK	2A	Systemic therapy for metastatic disease: Squamous cell carcinoma. •Consider EGFR mutation and ALK testing especially in never smokers or small biopsy specimens, or mixed histology •EGFR+/- ALK testing should be conducted as part of multiplex/next-generation sequencing

NCCN Informatics Collaborations

- Active Health
- Advocate Healthcare
- CareCore National, LLC
- Computer Sciences Corporation
- Corporate Care Management
- DK Pierce & Associates, Inc.
- DNA Direct
- Epocrates
- eviti
- Equicare Health
- Genospace
- Hines
- IBM Watson
- Interlink
- inVentiv
- Ion
- Magellan Health
- McKesson Health Solutions
- McKesson Specialty Health
- New Century Health
- Oncology Analytics
- On Q Health
- Optum
- Patients with Power
- Prime Therapeutics
- Presence Health
- Rush University Medical Center
- Skyscape
- UnitedHealthCare
- Zynx Health Inc.

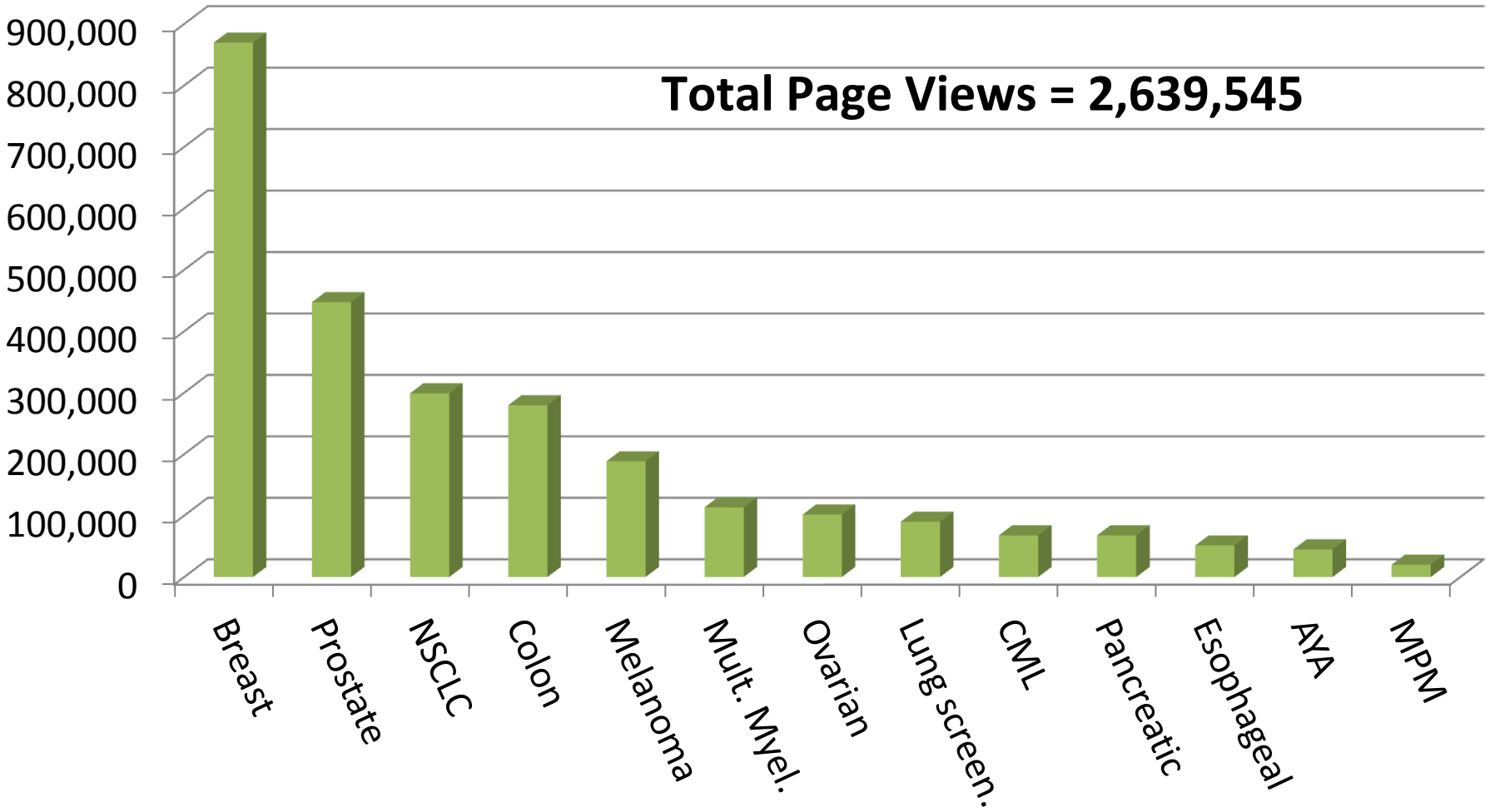
NCCN NATIONAL COMPREHENSIVE CANCER NETWORK FOUNDATION®
Guiding Treatment, Changing Lives.

NCCN Guidelines for Patients®

NCCN NATIONAL COMPREHENSIVE CANCER NETWORK FOUNDATION®
Guiding Treatment, Changing Lives.

NCCN Guidelines for Patients®

2013 Total Page Views on NCCN.org/.com



NCCN Process: Identification of Discussion Items

- Staff literature search for clinical trials reports
- NCCN institutional review
- Panel member review
- Patient advocacy review
- Pharmaceutical industry and payor requests
- Community oncology requests
- Individual recommendations

NCCN Guidelines®

- Evidence-based consensus process for development
- Multidisciplinary panels
- Multiple sources of input of information to be considered
- Conflicts of interest tightly managed
- Make recommendations across the continuum of care
- Continuously updated
- Define the standard of cancer care and coverage within the USA
- Basis of multiple NCCN programs and initiatives