NCCN National Comprehensive Cancer Network®

www.nccn.org

NCCN Oncology Outcomes Database Project

Joan McClure

January 2008

DRAFT – Confidential – For Internal Use Only

NCCN National Comprehensive Cancer Network®

NCCN Oncology Outcomes Project Update

Project	Start	Patients	Institutions
Breast Cancer	7/1997	34,000	13 NCCN 8 community

DRAFT – Confidential – For Internal Use Only

Goals of the NCCN Outcomes Research Project

- Identify the most efficacious and cost-effective strategies for the management of common oncologic conditions
- Monitor & benchmark concordance with guidelines in our member institutions
- Describe patterns and outcomes of care
- Create a feedback loop to physicians, institutions, guideline development

DRAFT – Confidential – For Internal Use Only

Overview of Data Collection

DRAFT – Confidential – For Internal Use Only

Eligibility Criteria

Breast Cancer Database
• Newly diagnosed; • Some or all care received at participating institution

DRAFT – Confidential – For Internal Use Only

Collection of Disease Details

Breast Cancer	
Staging & Follow-up Tests	**Staging & Follow-up**
Markers	**ER, PR, HER2/neu at diagnosis and metastases**
Staging	**Clinical and path, T-size, involved nodes**
Pathology	**Histology, grade**

DRAFT – Confidential – For Internal Use Only

Collection of Treatment Details

Breast Cancer Therapy	
Drug Tx	**Generic Name** **Duration** **Response** **Protocol**
Growth Factors	
RT	**Intent** **Duration** **Response** **Protocol**
Surgery	**Procedure** **Date** **Protocol**

DRAFT – Confidential – For Internal Use Only

NCCN Patient Identification Number: __ __ __ __ __ __

NSCLC: TREATMENT FORM
DRUG THERAPY: First Regimen Information

Directive: *For each drug or combination of drugs administered at the NCCN institution for the NSCLC diagnoses recorded on the TREATMENT: DRUG THERAPY form with a Drug Therapy ID, record detailed information about each drug including first and last dose, dates, etc. Record one agent per row. Copy form if additional entries are required.*

Patient Institution Number: ☐☐ (2=DFCI, 4=MDA, 5=RPCI, 8=UMICH, DUKE, JHU)

NCCN Patient Identification Number: ☐☐☐☐☐☐

Drug Tx ID *Record procid for the regimen associated with each drug*	Drug ID *Uniquely number each drug in the regimen*	Drug Code *Record the chemotherapy from the choice list*	Route -1=Unk 0=Other 2=IV, NOS 3=IV, bolus 4=IV contin 5=Subcut 6=Oral	First ECOG PS -1=Unk 0 1 2 3 4 5	First Dose Start Date mm/dd/yyyy	First Dose Est Start Date? 0=No 1=Yes	First Dose Overall Amount -1=Unk Amount	First Dose Overall Parameters -1=Unknown 0=Other, specify 1=mg/mm2 2=mg 3=AUC 4=mg/kg 5=mcg/kg	First Patient Parameter -1=Unknown 0=Other, specify 1=Weight in kg, specify 2=BSA, specify	First Patient Weight, kg -1=Unk OR Pt weight	First Pt BSA -1=Unk OR Patient BSA	First Dose Administered -1=Unk OR Amount admin	Unit of First Admin Dose -1=Unknown 0=Other, specify 1=mg/mm2 2=mg 3=AUC 4=mg/kg 5=mcg/kg

Last Dose End Date
mm/dd/yyyy
	Last ECOG PS
	-1=Unk
	0
	1
	2
	3
	4
	5
		Last Dose Est. End Date?
		1=Yes
			Last Dose Amount
			-1=Unk
			Amount
				Last Overall Dose Parameters
				-1=Unknown
				0=Other, specify
				1=mg/mm2
				2=mg
				3=AUC
				4=mg/kg
				5=mcg/kg
					Last Patient Parameter
					-1=Unknown
					0=Other, specify
					1=Weight in kg, specify
					2=BSA, specify
						Last Patient Weight, kg
						-1=Unknown
						OR
						Patient weight
							Last Patient BSA
							-1=Unk
							OR
							Patient BSA
								Last Dose Administered
								-1=Unknown
								OR
								Amount admin
									Unit of Last Administered Dose
									-1-1=Unknown
									0=Other, specify
									1=mg/mm2
									2=mg
									3=AUC
									4=mg/kg
									5=mcg/kg
										# Doses Given
										-1=Unk
										OR
										Count of times drug administered to patient
											# doses given, est?
											1=Yes

CRA's Signature/Date: _____

07/11/2007

Copyright ©2007 National Comprehensive Cancer Network (NCCN)

Collection of Outcomes

Breast Cancer	
Disease	**Metastatic sites/date** **Best Response to tx**
Survival	**NCCN date** **Contact date** **Death date***
Medical Events	
Other	

TR, SSDI, NDI confirmation

DRAFT – Confidential – For Internal Use Only

Treatment Related Complications

DRAFT - CONFIDENTIAL- For Internal Use Only

Patient Initials: ___ , ___ (first, last) **Medical Record Number**: _____

NSCLC: MEDICAL EVENTS

Directive: All charts reviewed should be examined for medical events. There is no hierarchy of sources for medical events data. Select the appropriate medical events from the code list. If several medical events are found, then complete the table for each medical event separately. Record each event only once the first time that it occurs; collect events occurring three months (90 days) prior to the lung cancer diagnosis. Copy form if additional entries are required.

Patient Institution Number: ☐☐☐ (2=DFCI, 4=MDA, 5=RPCI, 8=UMICH, 14=DUKE, 17=JHU)

NCCN Patient Identification Number: ☐☐☐☐☐☐

Event ID	Event Code	Event Date (mm/dd/yyyy)	Event Date Estimated? 0=No 1=Yes	Medical Event Attributed to: -2=Not applicable -1=Unknown 0=Other 1=Surgery 2=Drug 3=Radiation therapy 4=Disease Progression

Treatment Related Complications - continued

Medical Event Codes

13=Anemia requiring hospitalization
29=Anemia requiring transfusion
4=Bleeding requiring hospitalization
Bronchopleural fistula
24=Acute renal failure: dialysis +/- creatinine>6.0
25=Admission to hospice
26=Admission to ICU
27=Admission to nursing home
30=Angina-new or unstable
Aspiration
Atrial fibrillation
32=CHF
COPD exacerbation
33=CVA/Stroke/TIA
Carcinomatous meningitis
34=Cardiac Arrest
Chylothorax
Cushing's syndrome
35=Deep wound infection
Discussion re: admission to nursing home
Discussion re: DNR order
Discussion re Hospice care
Discussion re palliative care
Discussion re venue for dying
Dyspnea requiring hospitalization
16=Dehydration requiring hospitalization
17=Diarrhea requiring hospitalization
37=DNR
53=DVT (may or may not require hospitalization)
36=Delirium
1=Febrile neutropenia – outpatient management
2=Febrile neutropenia – requiring hospitalization
Headache
Hemoptysis
Home oxygen therapy
Hypercalcemia
Hypertrophic pulmonary osteoarthropathy
Impending fracture
3=Infection requiring hospitalization
39=Indwelling venous catheter clot
47=MI
15=Mucositis requiring hospitalization
19=Nausea and vomiting requiring hospitalization
48=Neuropathy
Neurologic compromise
0=Other, specify
Pain requiring hospitalization
Pathologic fracture
Pericardial effusion/tamponade
Pleural effusion, non-malignant
54=Pneumonia (may or may not require hospitalization)
Pneumothorax requiring chest tube
55=Pulmonary Embolus (may or may not require hospitalization)
49=Respiratory failure requiring intubation
Radiation pneumonitis
50=Sepsis
Syndrome of inappropriate antidiuretic hormone secretion (SIADH)
SVC syndrome
Seizure
Spinal cord compression
12=Thrombocytopenia requiring hospitalization
51=Thrombocytopenia requiring transfusion

DRAFT

Examples of Studies Supported by the Database

- Benchmarking practice patterns and developing tools to support appropriate health plan budgeting
- Conducting "real-world" assessments of clinical effectiveness, tolerability and comparative clinical benefit outside the artificially controlled context of blinded clinical trials
- Evaluating utilization trends associated with evolving therapeutic technologies
- Developing descriptive demographics of cancer patients

DRAFT – Confidential – For Internal Use Only

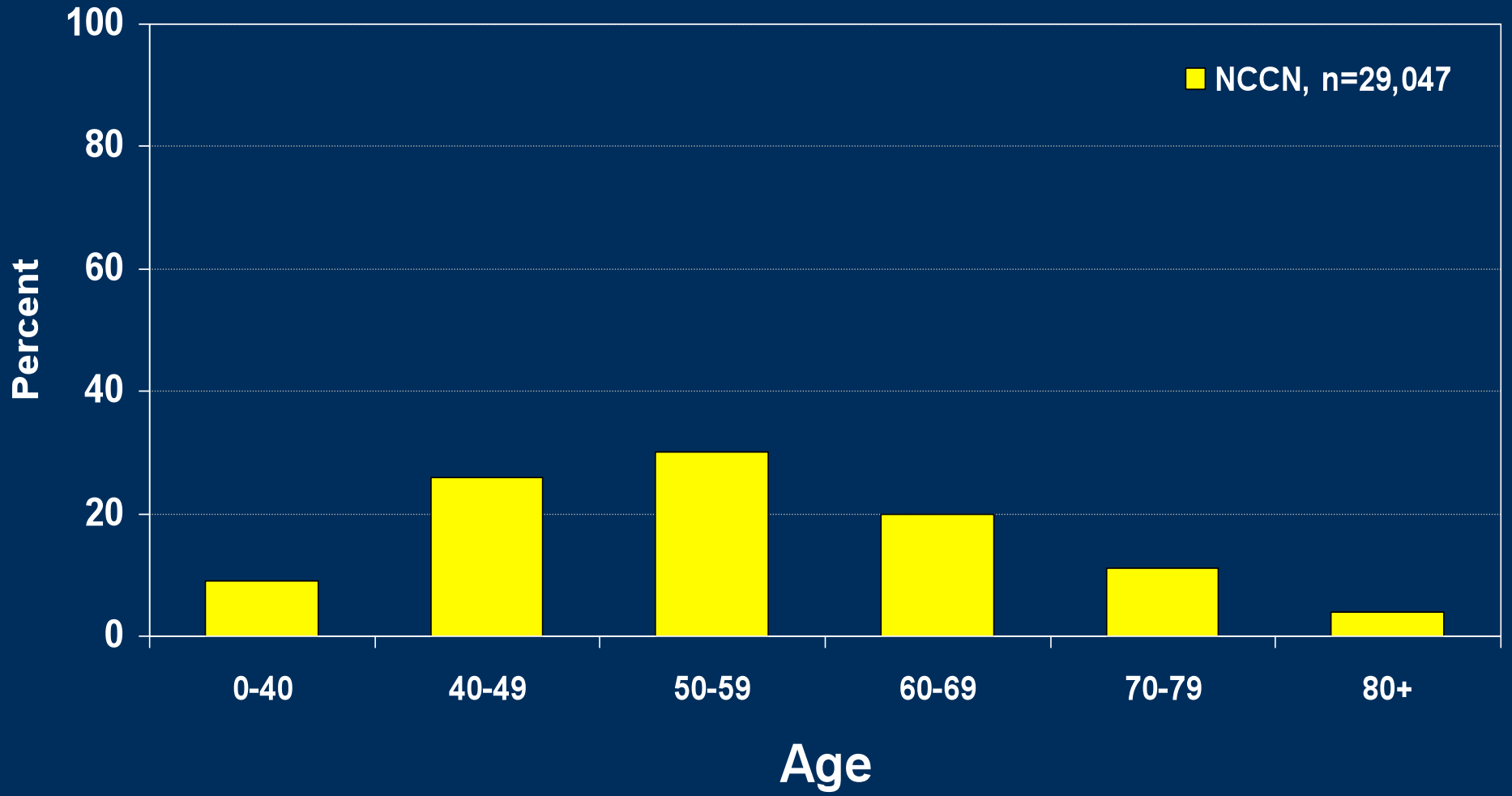
NCCN Oncology Outcomes Database Project

Breast Cancer Data Analysis

- Based upon the 10 institutions from the NCCN Breast Cancer Database
- Includes Unless otherwise noted, the cohort runs from those patients presenting to the NCCN institution between July 1, 1997 – February 3, 2007 (n=29,047) divided into four categories:
  - All NCCN patients (n=29,047)
  - Medicare (n=6,585)
  - Large private MCOs (n=10,894)
  - Other (n=4,635)

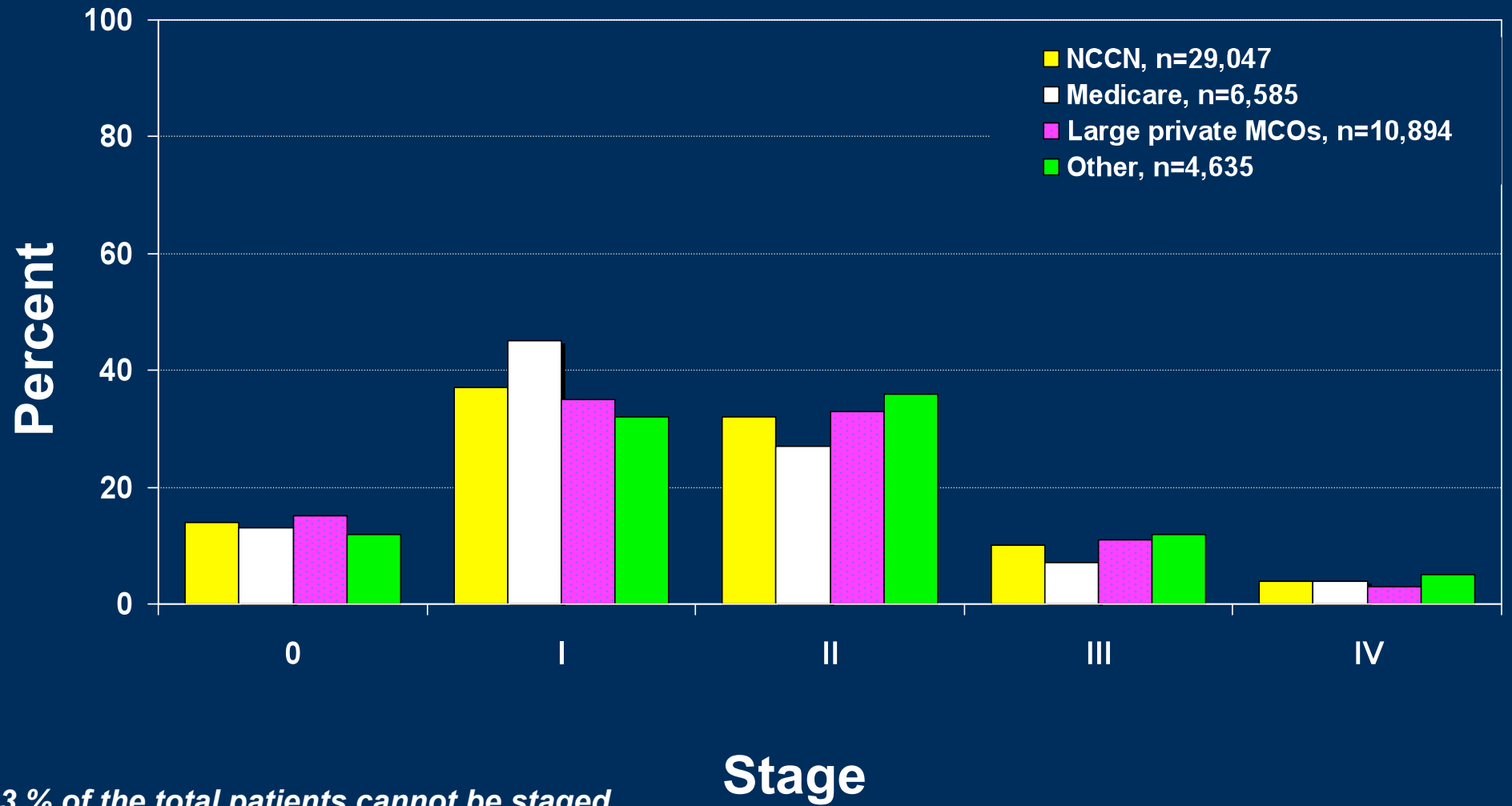
DRAFT – Confidential – For Internal Use Only

Age at Diagnosis Breast Cancer Patients



DRAFT – Confidential – For Internal Use Only

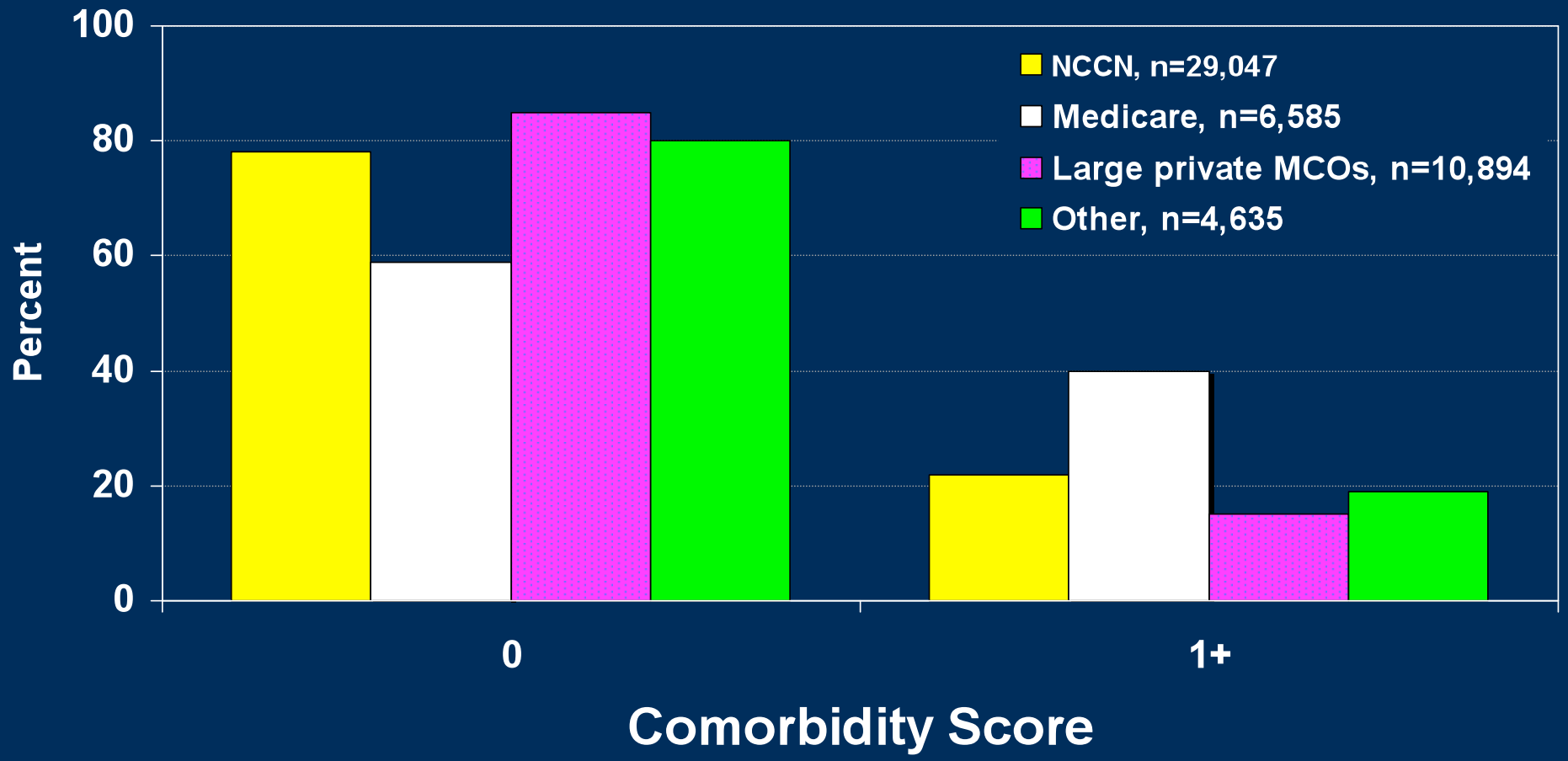
Stage at Diagnosis: Breast Cancer Patients



3 % of the total patients cannot be staged.

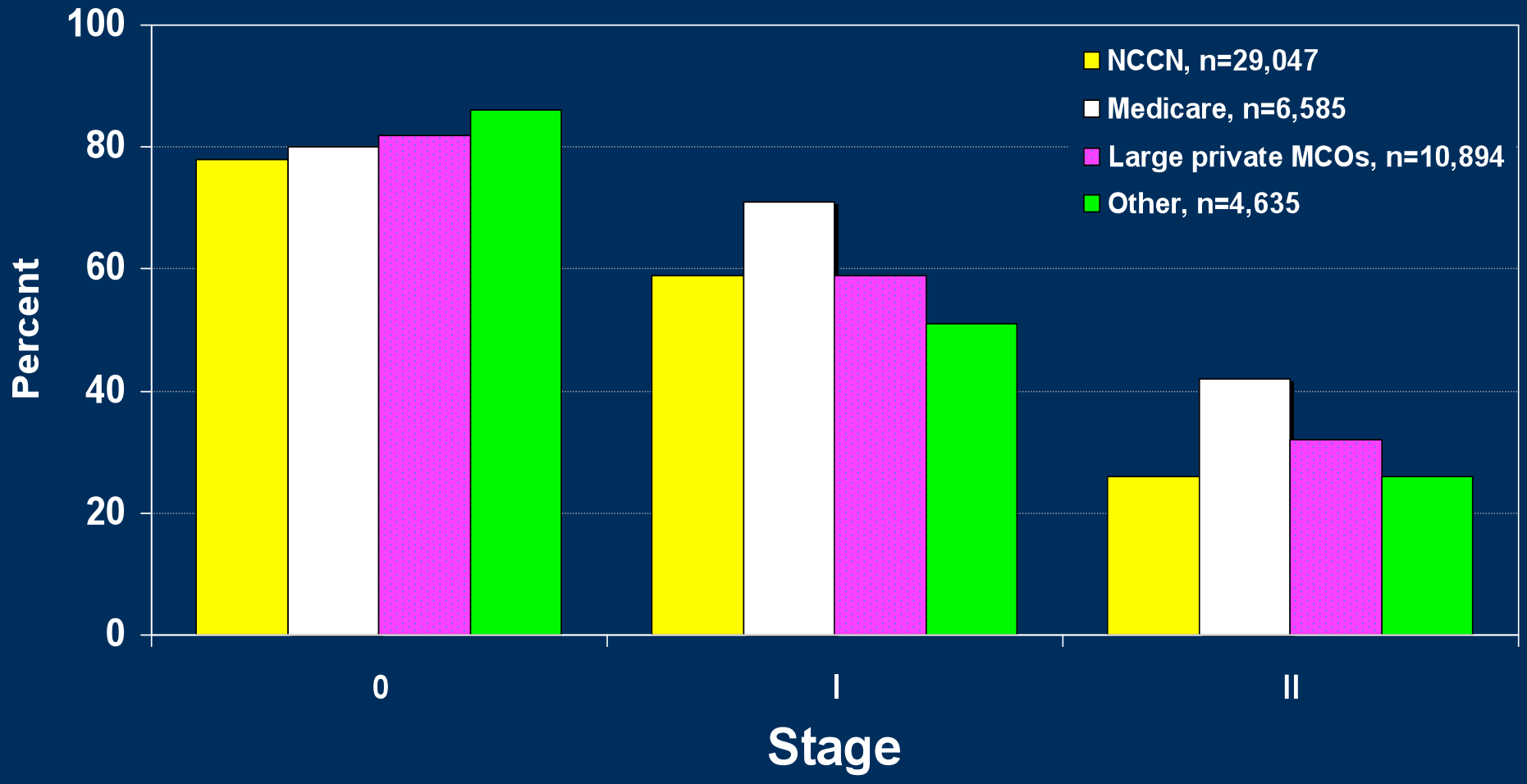
DRAFT – Confidential – For Internal Use Only

Comorbidity Score at Presentation



DRAFT – Confidential – For Internal Use Only

Screening Mammogram-Detected Breast Cancer



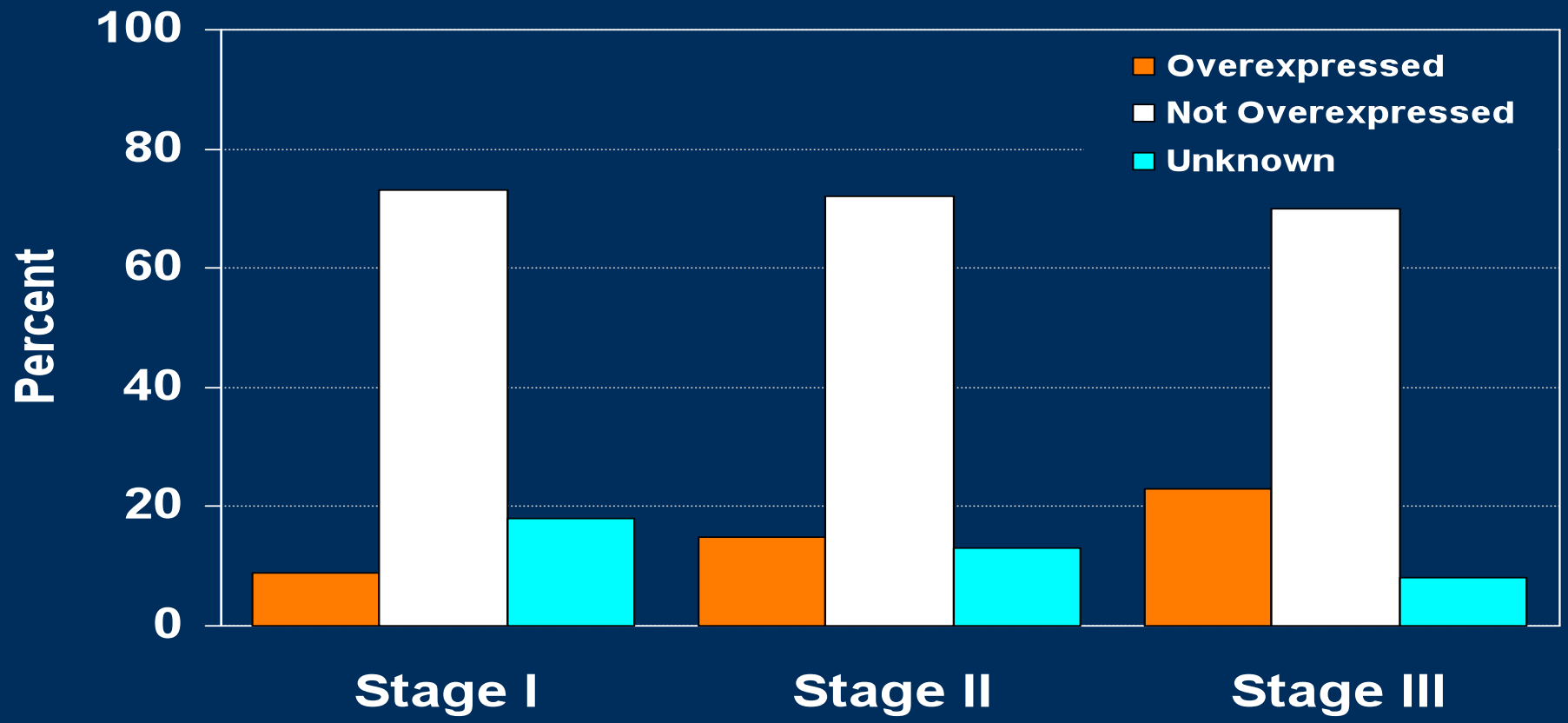
DRAFT – Confidential – For Internal Use Only

Adjuvant Chemotherapy and Hormone Therapy for NCCN Stage I/II Patients Receiving Therapy

Types of Adjuvant Therapy	Stage I n=8,789		Stage II n=7,919	
Anthracycline	9%	13%	9%	32%
Anthracycline + Taxane	3%		19%	
CMF-containing regimen	1%		1%	
Other regimen	<1%		3%	
Anthracycline + HT	17%	86%	19%	67%
Anthracycline + Taxane + HT	2%		30%	
CMF + HT	3%		4%	
Other + HT	1%		1%	
HT alone	62%		13%	

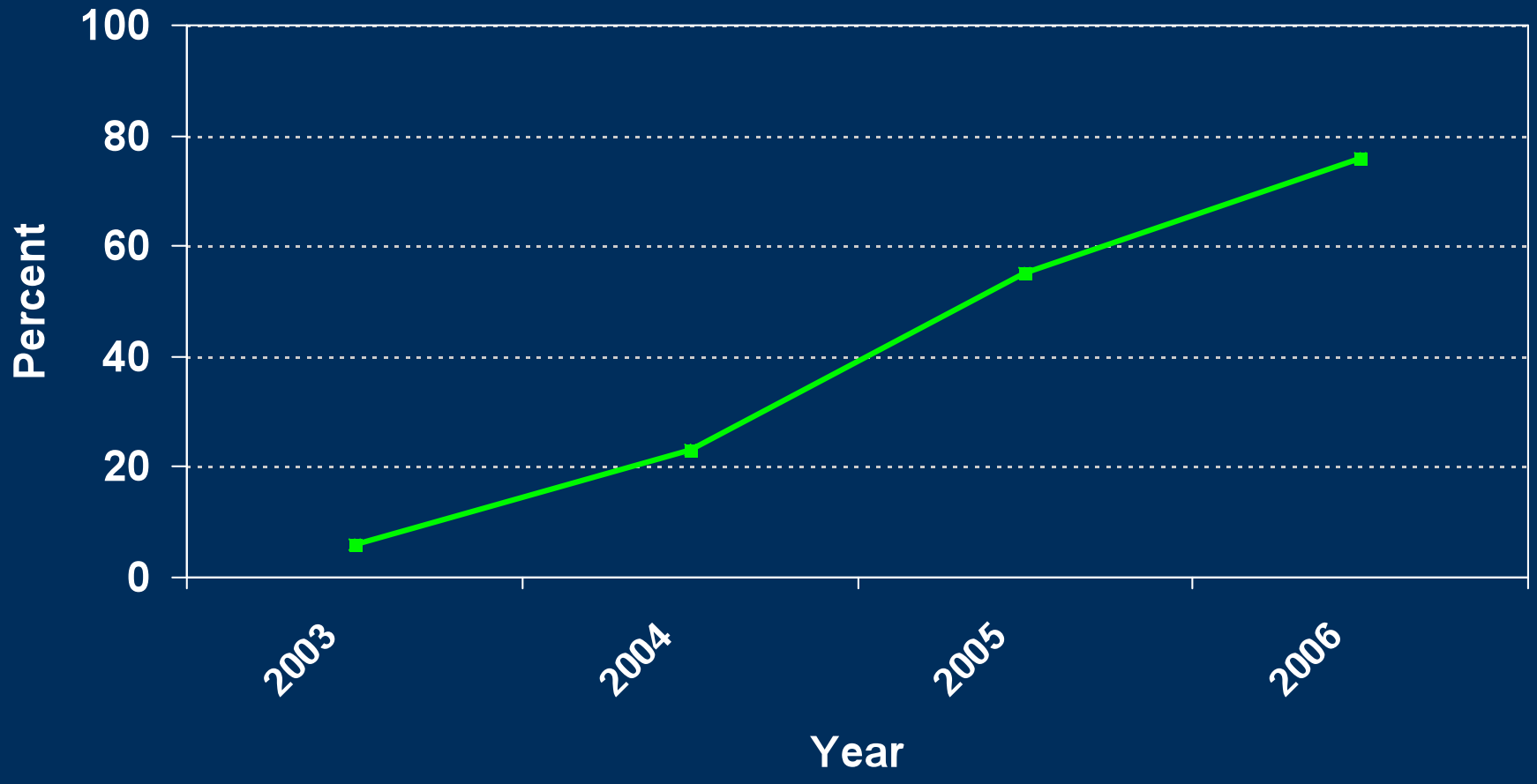
DRAFT – Confidential – For Internal Use Only

HER2/neu Overexpression by Stage at Diagnosis, n=27,157 (July 1999 – March 2007)



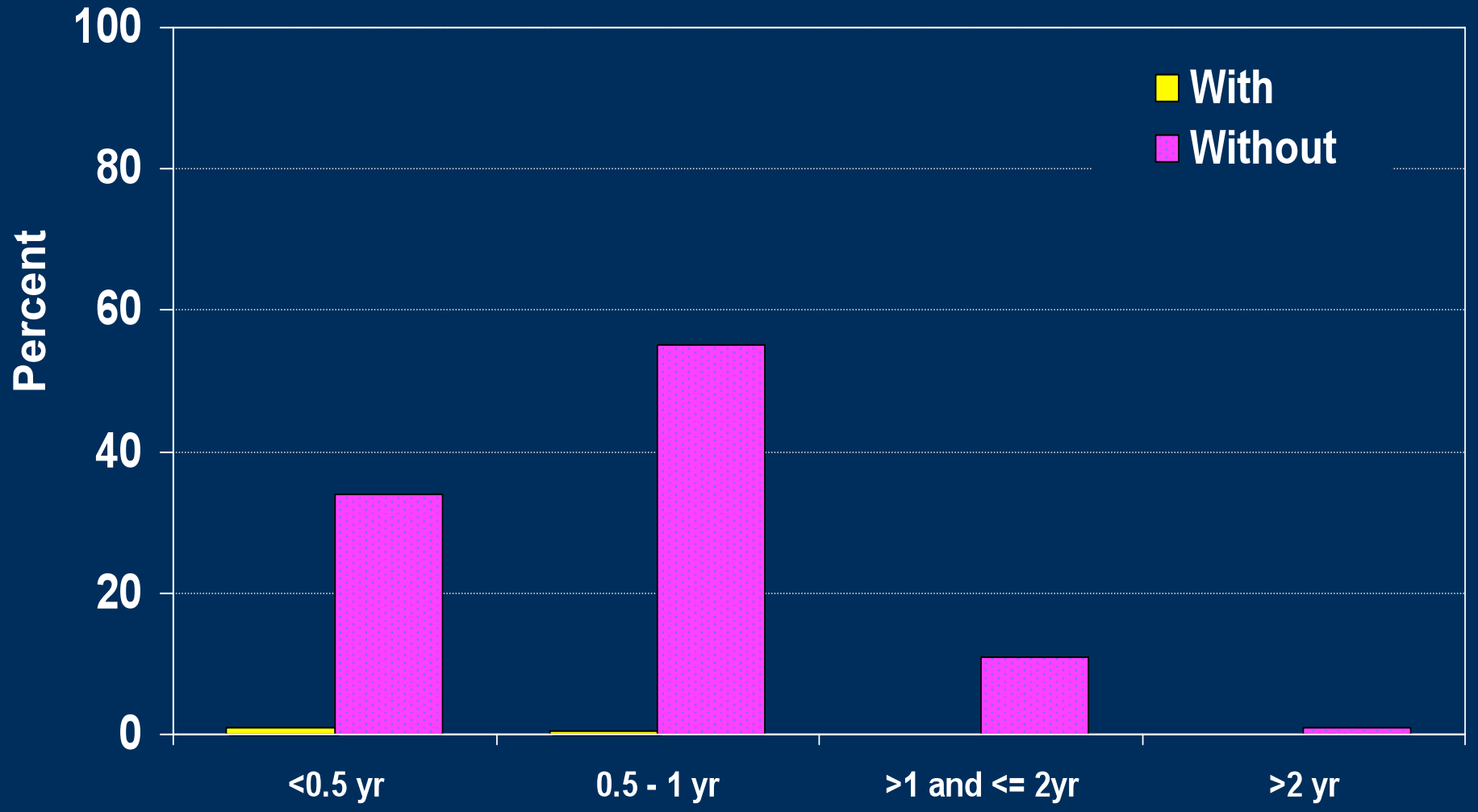
DRAFT – Confidential – For Internal Use Only

Adjuvant Trastuzumab Use Off Protocol in Stage I/II Patients with HER2/neu Overexpression (2003 – 2006)



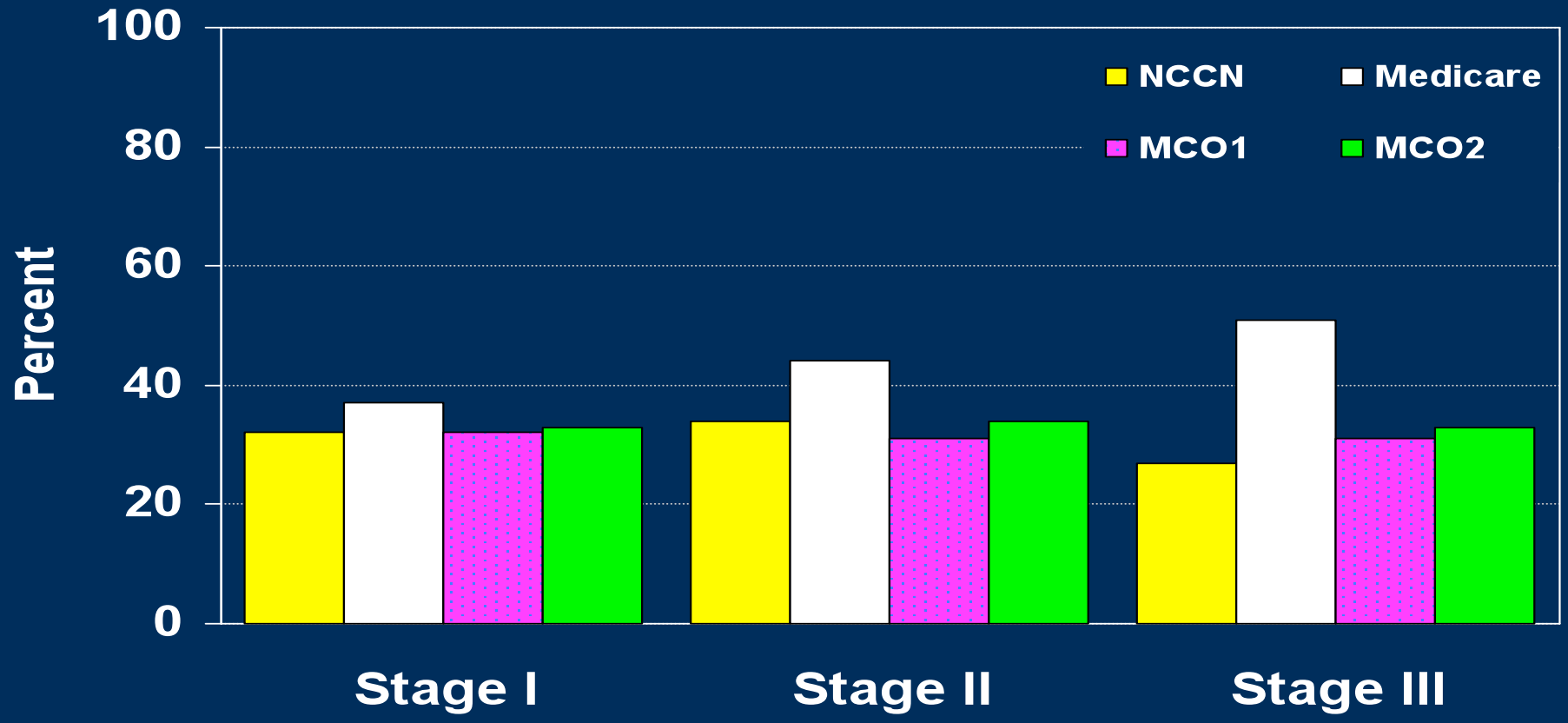
DRAFT – Confidential – For Internal Use Only

Duration of Trastuzumab Administration in the Adjuvant Setting by CV Morbidity at Presentation



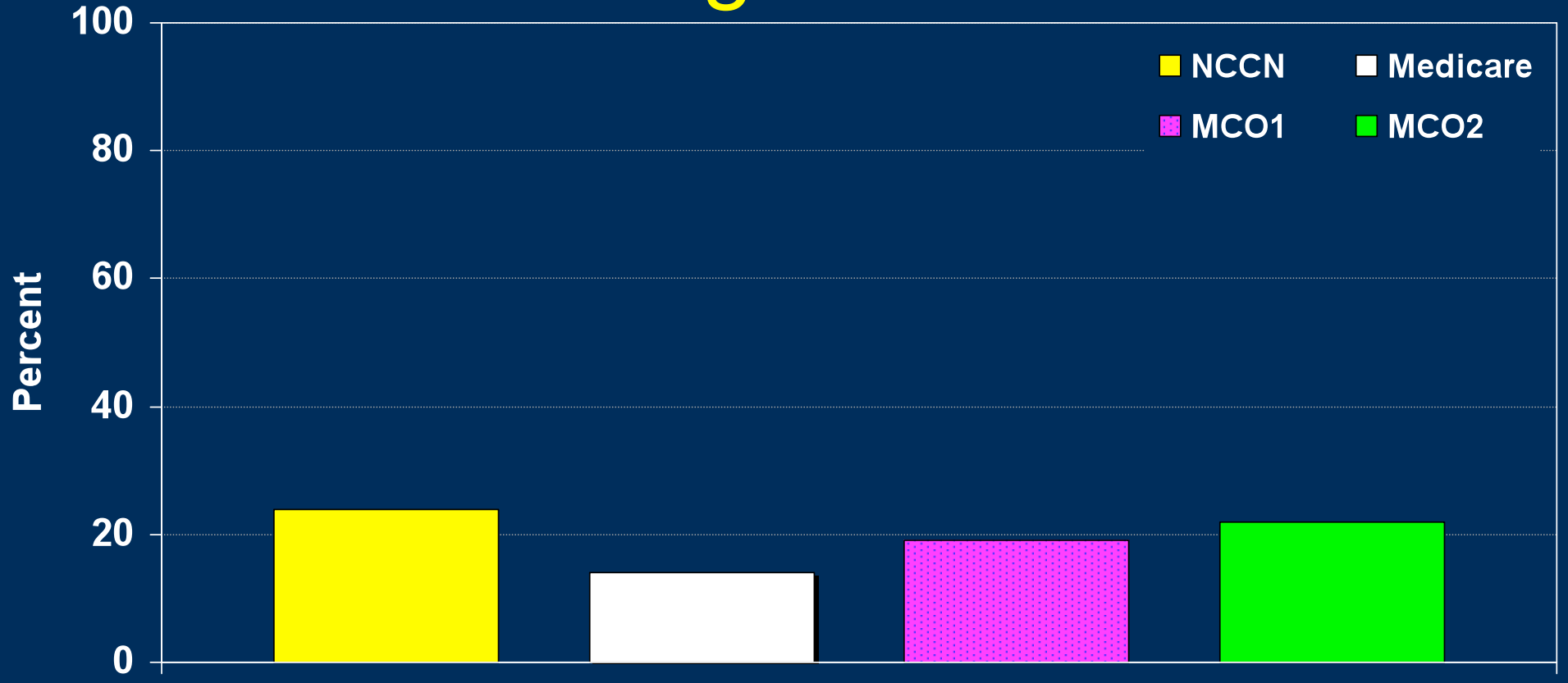
DRAFT – Confidential – For Internal Use Only

Receipt of Aromatase Inhibitors in Adjuvant Setting: Post Menopausal Stage I – III HR+ Patients, n=9,917 (Jan 2002 – Feb 2007)



DRAFT – Confidential – For Internal Use Only

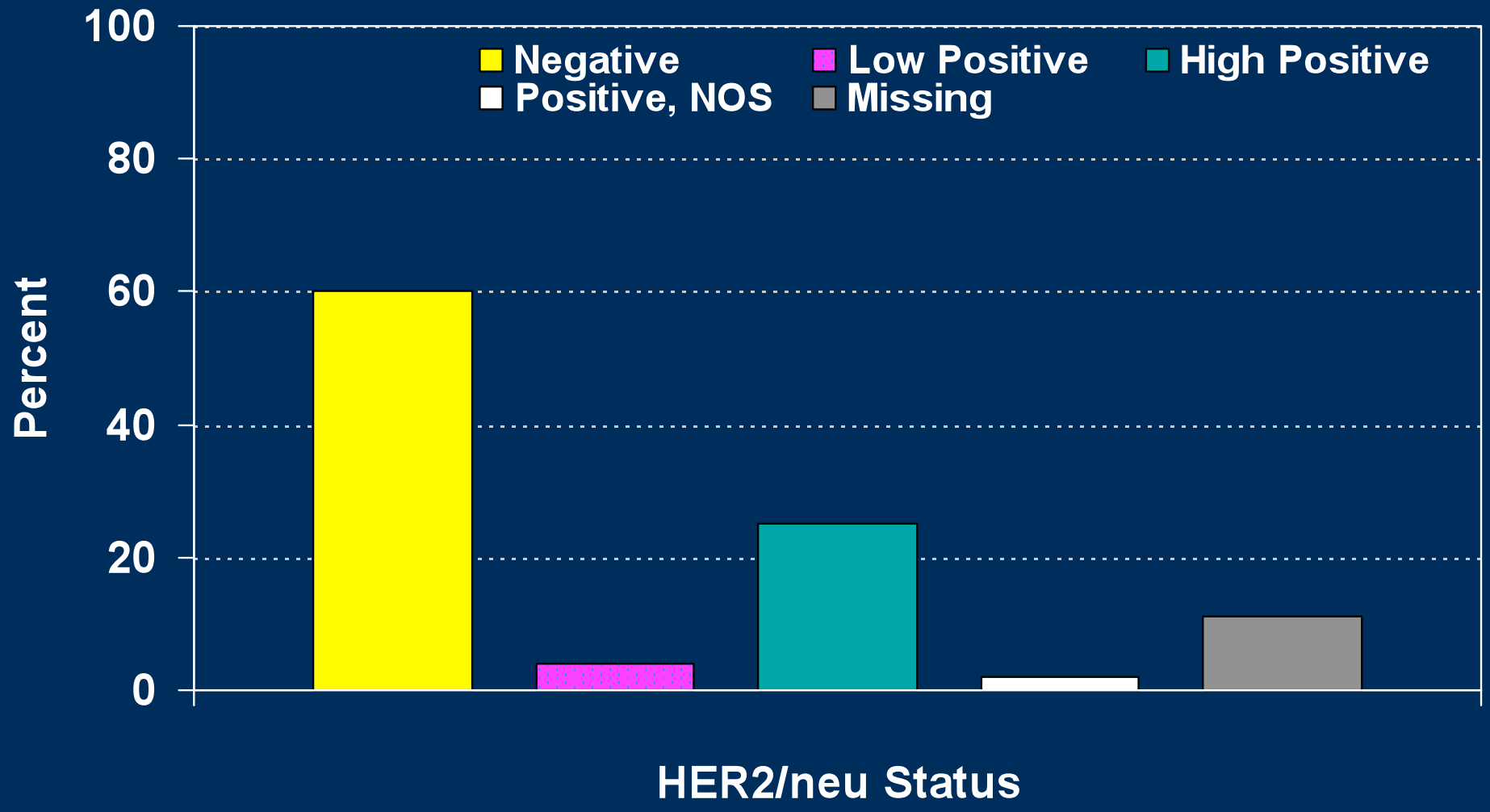
Patients on Clinical Trials, Stages I-III



In multivariable logistic regression, MCO1 and Medicare significantly less likely to participate controlling for NCCN center and stage of BCA.

DRAFT – Confidential – For Internal Use Only

HER2/neu Status in Patients with Distant Metastases (n=2,664)



DRAFT – Confidential – For Internal Use Only

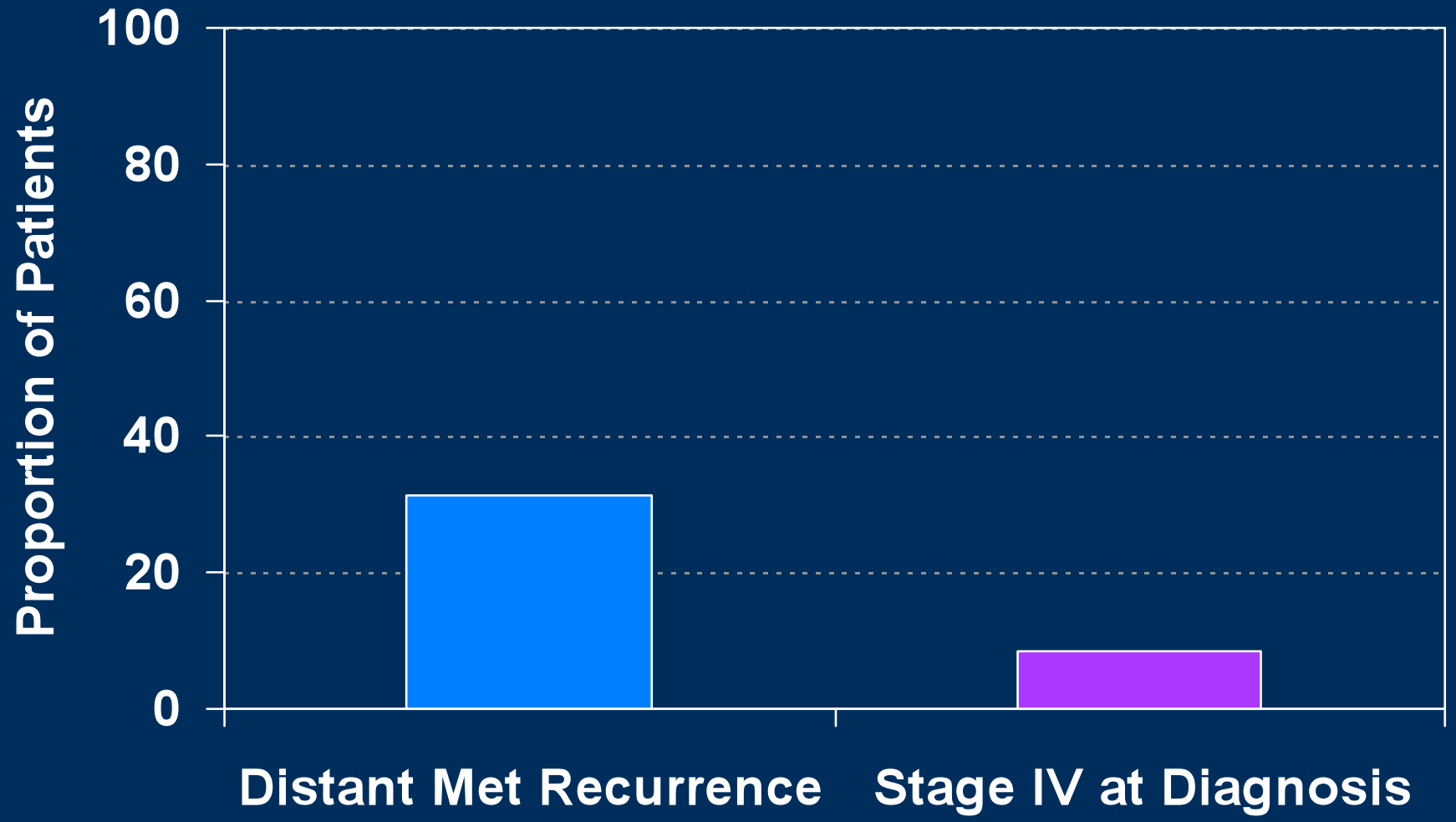
Stage IV at Initial Diagnosis: Type of First-line Chemotherapy (n=967)

Types of First-Line Therapy	%
Anthracycline	21%
Anthracycline + Trastuzumab	1%
Anthracycline + Taxane	10%
Taxane +/- HT	14%
Taxane + Trastuzumab	7%
Trastuzumab +/- HT	4%
Other Single Agent/Regimen +/- HT	9%
Other Single Agent/Regimen +Trastuzumab	<1%
Hormone Therapy	35%

Other regimens/agents include: CMF, CEF, carboplatin, vinorelbine, gemcitabine, capecitabine, and clinical trial chemotherapies.

DRAFT – Confidential – For Internal Use Only

Trastuzumab Use
Patients with Metastatic Disease
HER2-Neu Low Positive

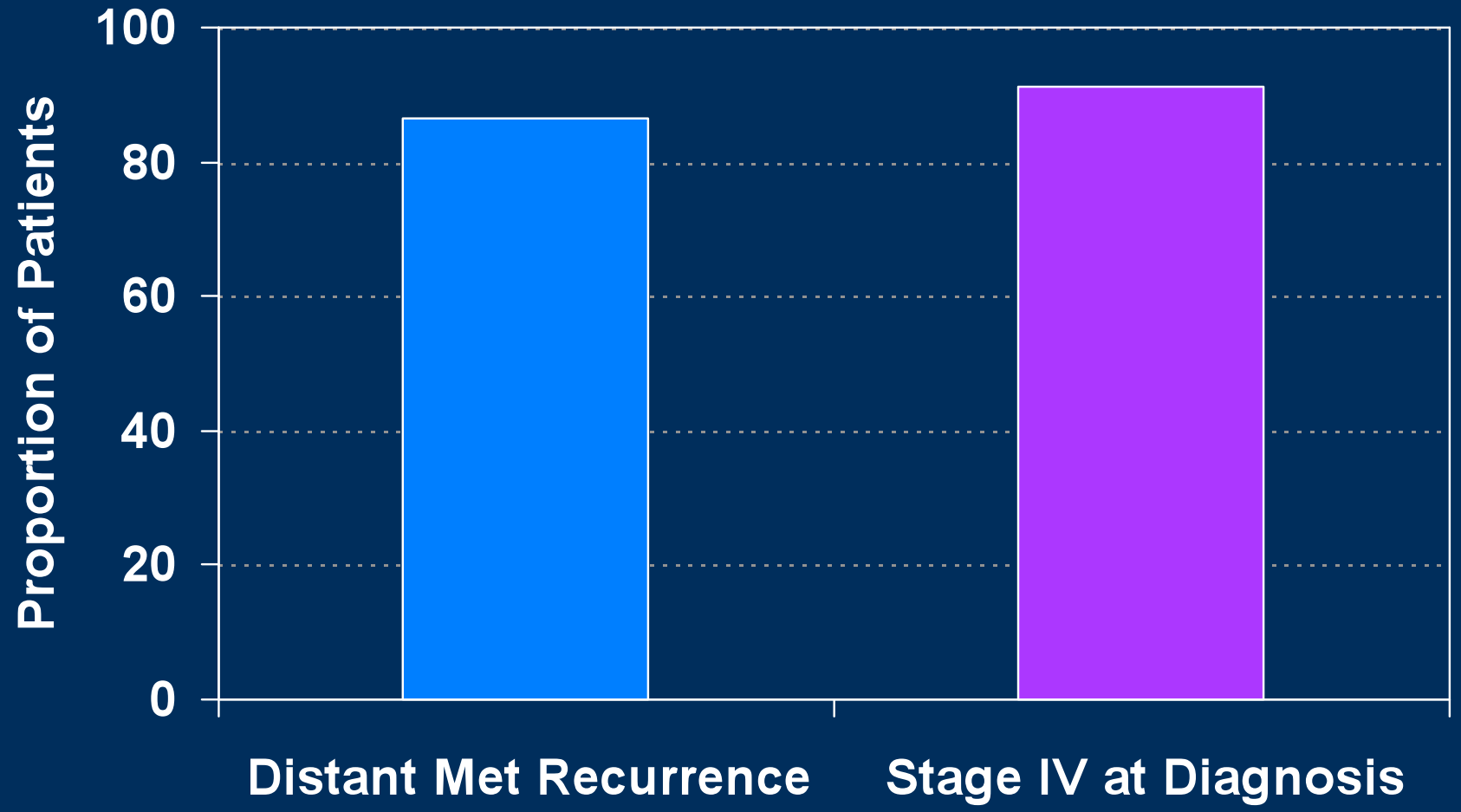


Confidential – For Internal Use Only

Cohort presenting 7/1/03-6/30/07

© NCCN All rights reserved.

Trastuzumab Use
Patients with Metastatic Disease
HER2-Neu High Positive

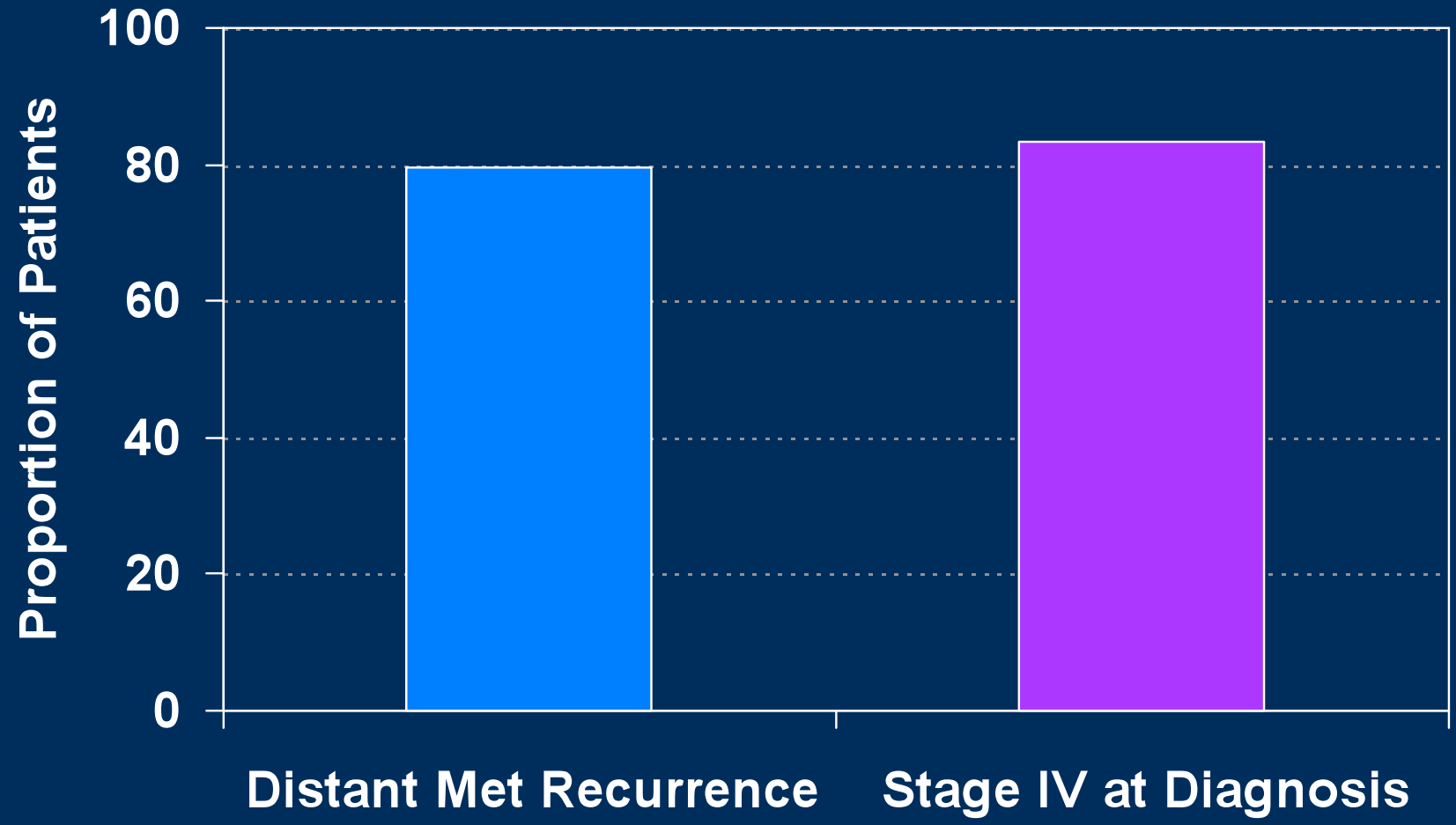


Cohort presenting 7/1/03-6/30/07

Confidential – For Internal Use Only

© NCCN All rights reserved.

Hormone Therapy
Patients with Metastatic Disease
Hormone Receptor Positive



Cohort presenting 7/1/03-6/30/07

Confidential – For Internal Use Only

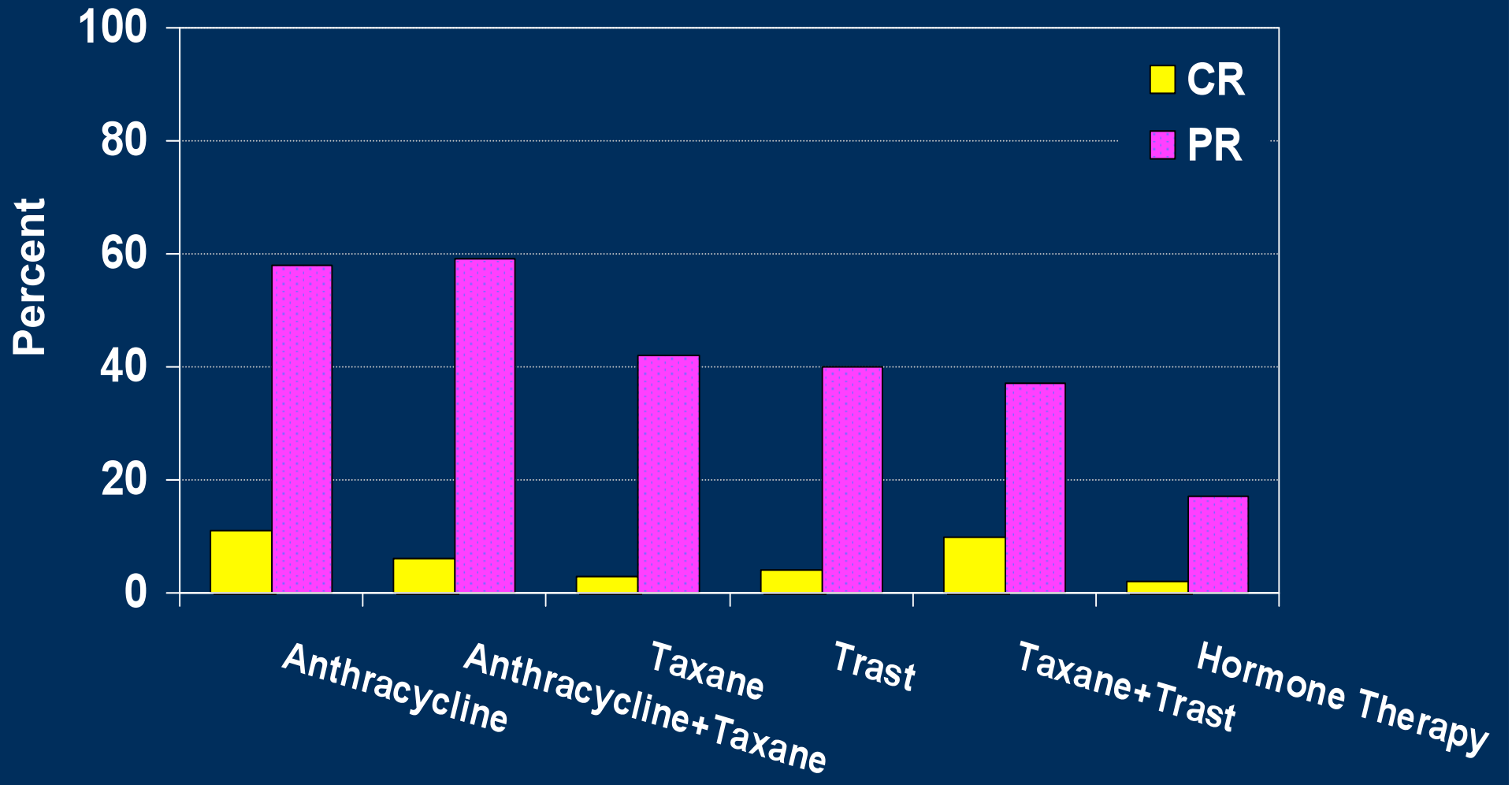
© NCCN All rights reserved.

Bevacizumab Use by Metastatic Site

Site	Bevacizumab Use
Ipsilateral breast	3 %
Chest wall	6 %
Bone	20 %
Lung	13 %
Liver	15 %
Brain	5 %
Lymph node, distant	8 %

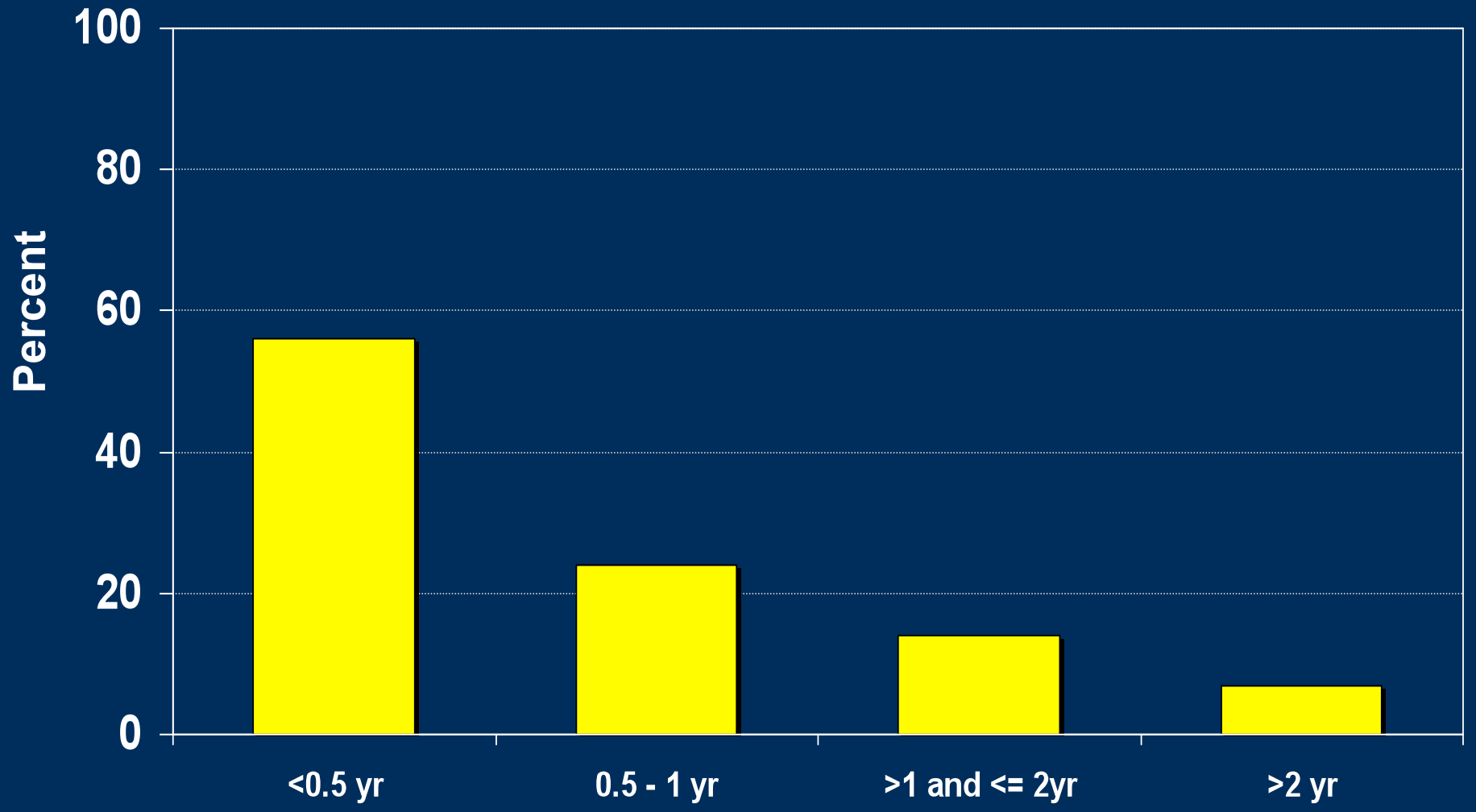
DRAFT – Confidential – For Internal Use Only

Stage IV (n=965) at Initial Dx: Response to First-Line Tx



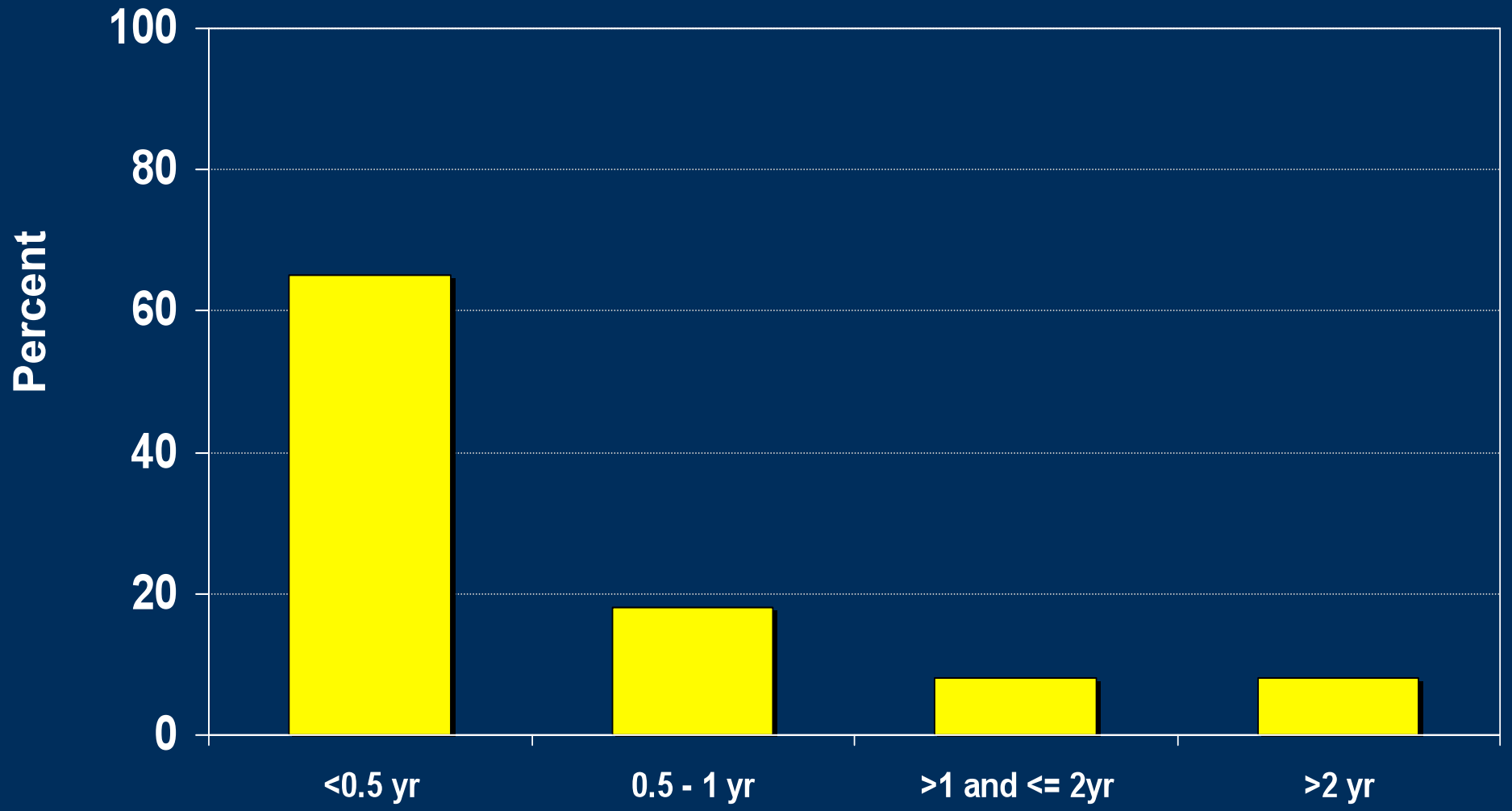
DRAFT – Confidential – For Internal Use Only

Duration of Trastuzumab Administration in the Metastatic Setting



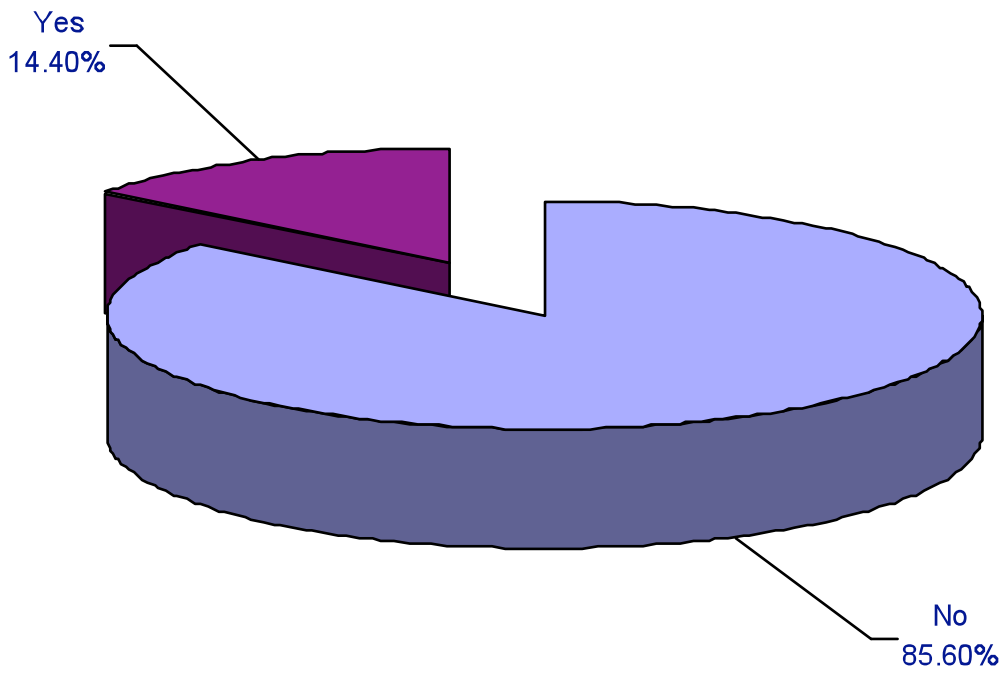
DRAFT – Confidential – For Internal Use Only

Disease Progression by the Duration of Trastuzumab Administration in the Metastatic Setting



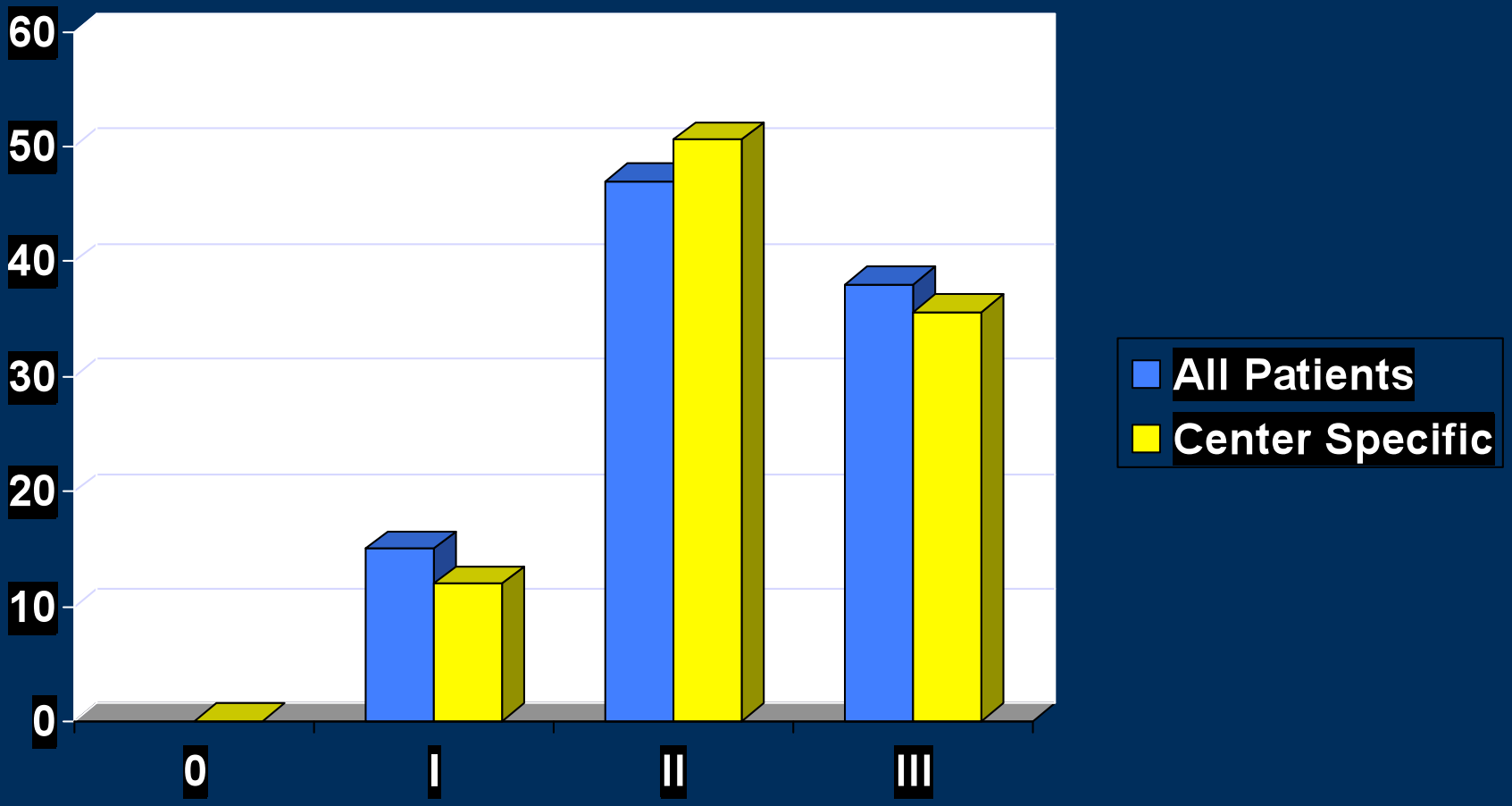
DRAFT – Confidential – For Internal Use Only

Use of Trastuzumab (First-Line) into Second-Line Therapy (n=551)



DRAFT – Confidential – For Internal Use Only

Patients with Metastatic Disease by Initial Stage at Diagnosis



DRAFT – Confidential – For Internal Use Only

Metastatic Recurrence: First-line Systemic Therapy (n=507)

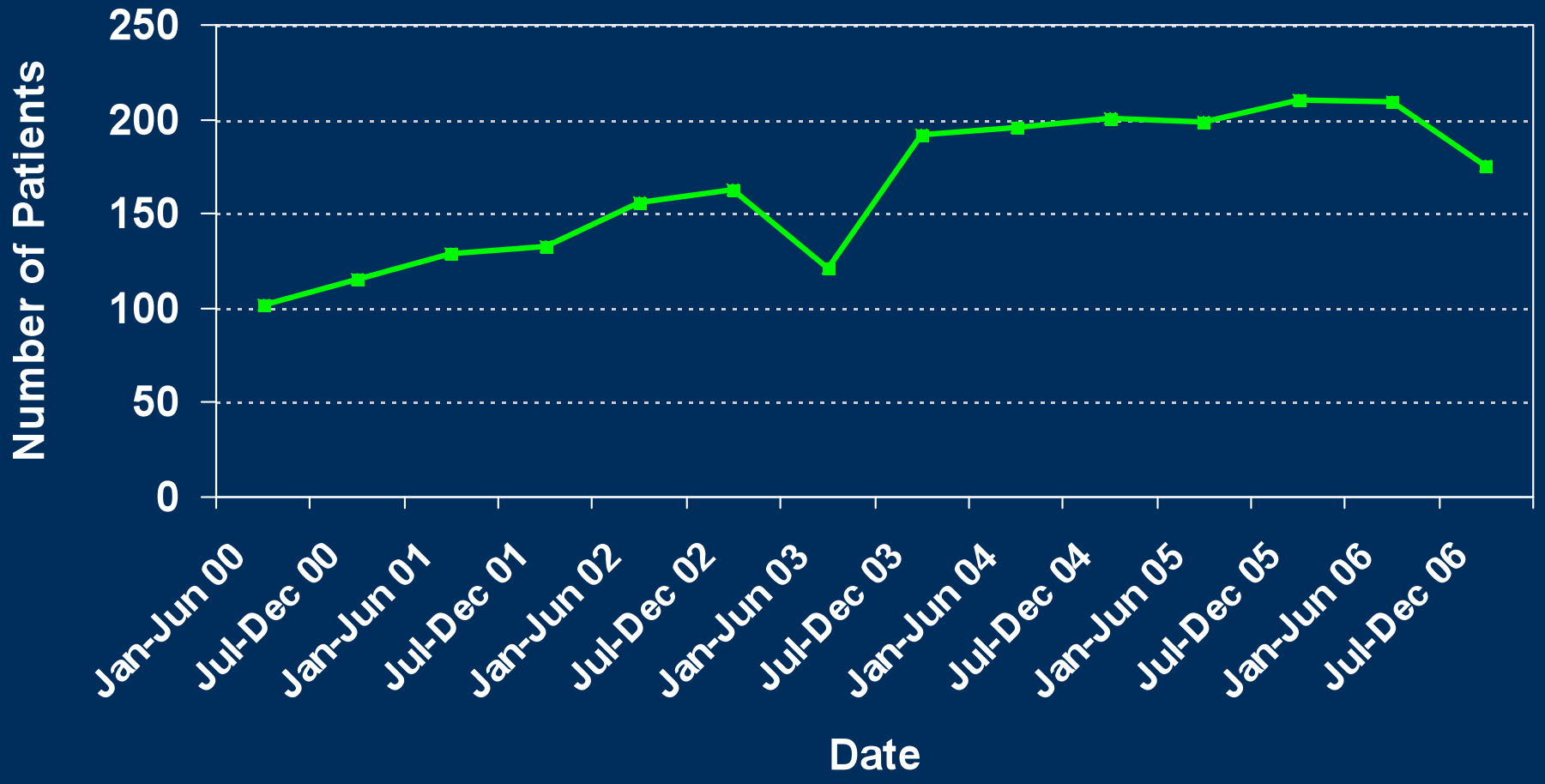
Types of First-Line Therapy	%
Chemotherapy	44%
Chemotherapy + Trast	15%
Trastazumab	2%
Hormone therapy	35%
Hormone therapy + Trastuzumab	1%
Chemotherapy + Hormone therapy	2%
Chemothrapy + Hormone therapy + Trastuzumab	<1%

Other regimens/agents include: CMF, CEF, carboplatin, vinorelbine, gemcitabine, capecitabine, and clinical trial chemotherapies.

Cohort presenting 7/1/03-6/30/07

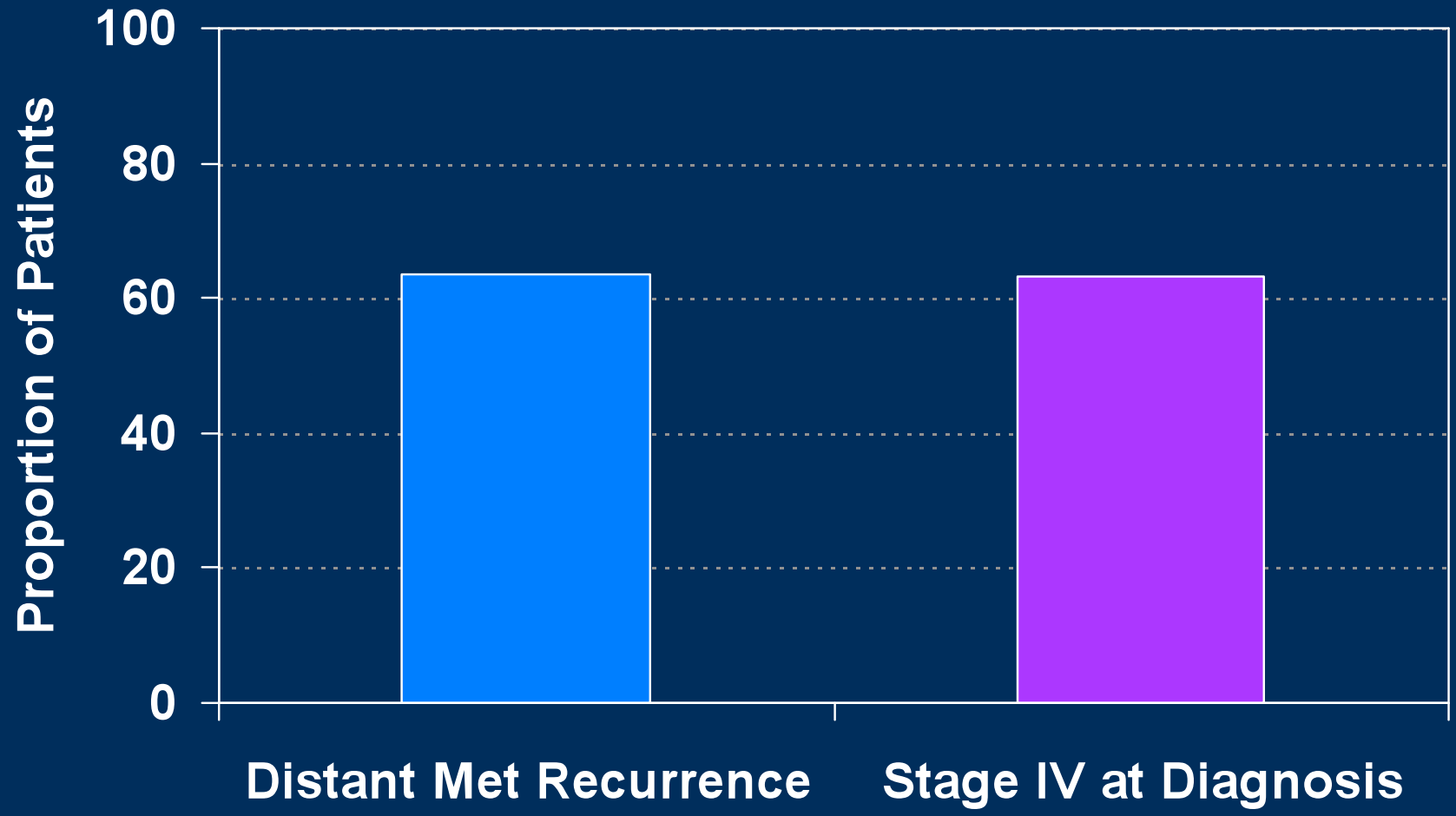
DRAFT – Confidential – For Internal Use Only

Capecitabine Use for Patients with Distant Metastases (2000-2006)



DRAFT – Confidential – For Internal Use Only

Bisphosphonates Use
Patients with Bone Metastases

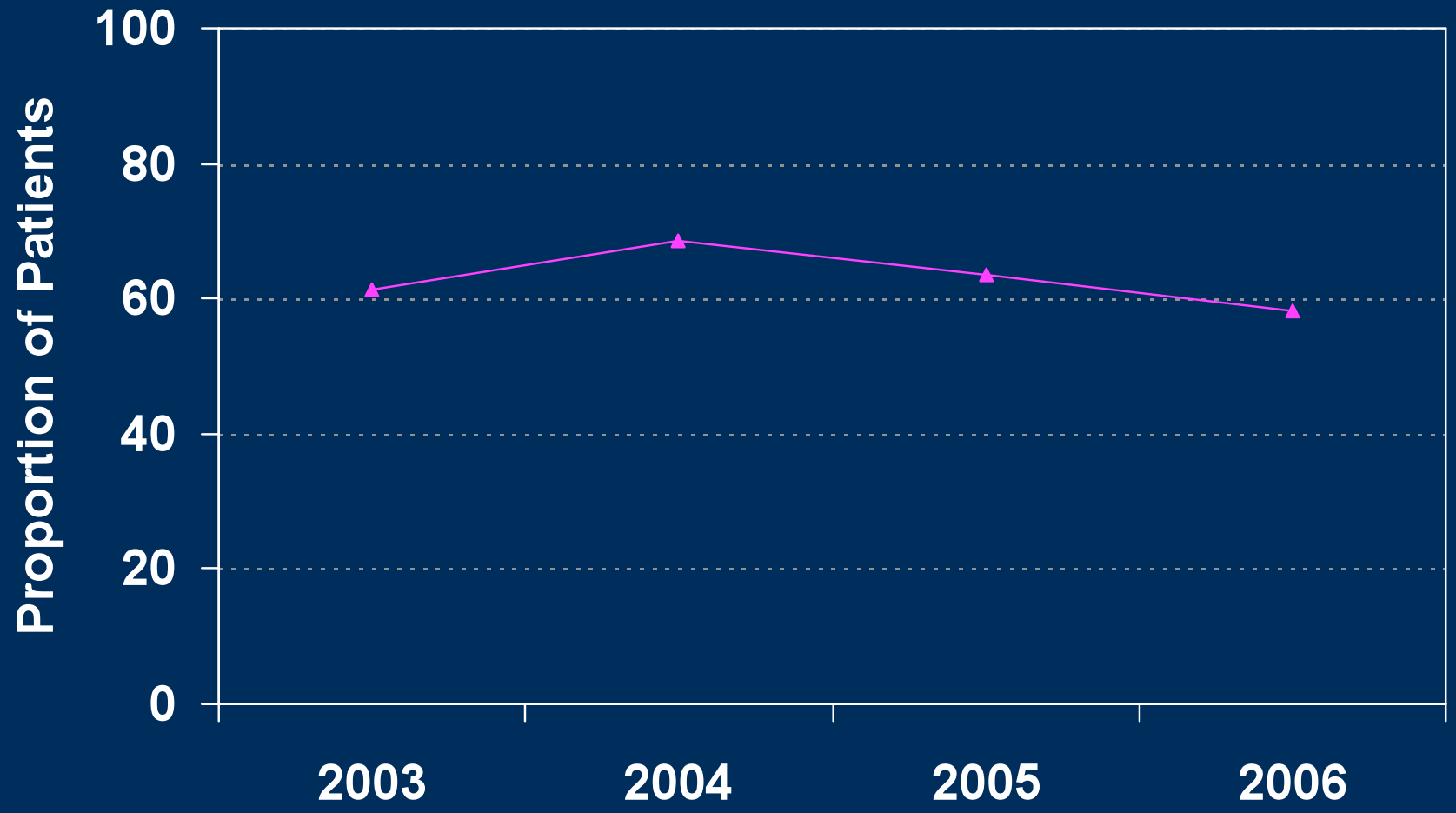


Confidential – For Internal Use Only

Cohort presenting 7/1/03-6/30/07

© NCCN All rights reserved.

Bisphosphonates Time Trend Patients with Bone Metastases who received Bisphosphonates

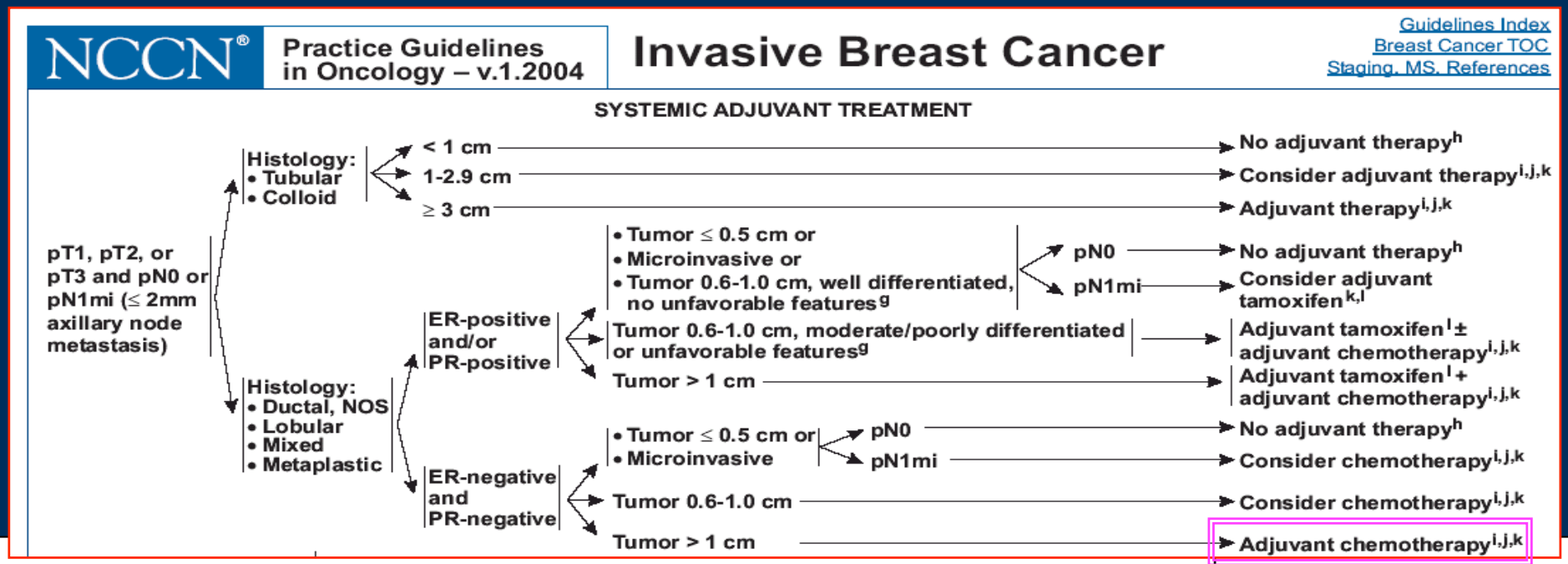


Confidential – For Internal Use Only

Cohort presenting 7/1/03-6/30/07

© NCCN All rights reserved.

Concordance: Institutional-Level Feedback



Label	Subgroup	*Recommended Treatment*	NCCN Patients N	Concordant Patients n	All Patients %	Center Ranges (low - high %)	MCO1 Patients N	MCO1 Concordant n	% MCO1 %
Stage I and II Chemo / Hormone Therapy									
5	Stage I/II, T > 1 cm, Node Negative or pN1mic, HR-	*Adjuvant Chemotherapy*	523	494	94%	(90 - 100)	247	228	92%

DRAFT – Confidential – For Internal Use Only

Concordance: Patient-Level Feedback to MD

NCCN BREAST CANCER PATIENT CONCORDANCE REPORT

Institution: NCCN Institution

Date Report Printed: 5/9/2005

This section to be completed only at patient's medical center:

Patient Name _____ Medical Record Number _____

PID: 689

DOB: 7/31/1915
Age: 89

DOD:

Demographics complete: Yes
Medical History complete: Yes

NCCN First Visit Date: 5/15/2001

Comorbidity: Yes: Renal disease, Rheumatoid arthritis

Date of Last NCCN Follow Up: 6/2/2004
Patient Data Censored: No

GUIDELINE CONCORDANCE INFORMATION

NCCN Guideline: *II node+ HR-* -- Stage II, Node Positive, Hormone Receptor Negative
Concordant: No
Guideline Version: 2000
Guideline Treatment Recommendation: Adjuvant Chemotherapy

Concordance analyses includes newly diagnosed breast cancer patients presenting to the NCCN between July 1, 1997 and November 20, 2003. Care was assessed against guideline in effect at the time the care was delivered (Version 1.1997 to 2001). Please note that those patients receiving care after June 30, 2002 are being assessed against Version 2001 guidelines until Version 2002 guidelines are implemented into the analyses.

PAST CANCER DIAGNOSES

Dx ID	Dx Date	Dx Type
(No Past Cancers)		

NCCN BREAST CANCER

Dx ID	Dx Date	Dx Type
1	4/26/2001	Malignant neoplasm of female breast

CHEMOTHERAPY AND HORMONE THERAPY

Dx ID	Proc ID	Therapy	Indication	Start Date (* If Estimated)	End Date (* If Estimated)	Response	Institution	On Protocol
(No Data Reported For This Section)								

DRAFT – Confidential – For Internal Use Only

Variation in Concordance

Center	Category 1 Mean % Concordance	Category 2A Mean % Concordance
A	90	72
B	90	71
C	89	73
D	91	65
E	91	64
F	91	60
G	84	65
H	81	59

Category 1: uniform NCCN consensus based on high-level evidence
Category 2A: uniform NCCN consensus based on lower-level evidence

DRAFT – Confidential – For Internal Use Only