

FDA-ASCO: Geriatric Oncology Workshop

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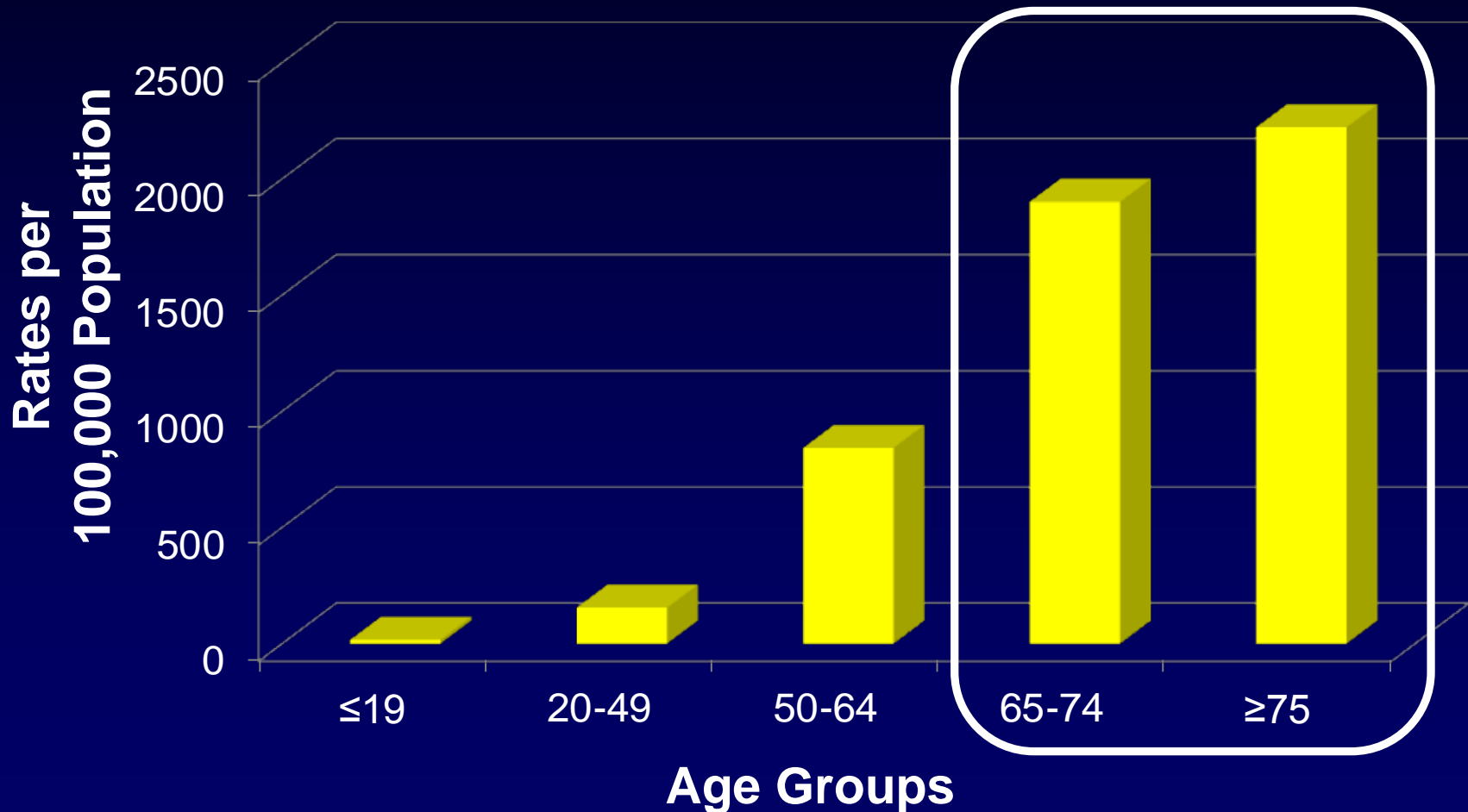
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City of Hope

Cancer is a Disease Associated with Aging

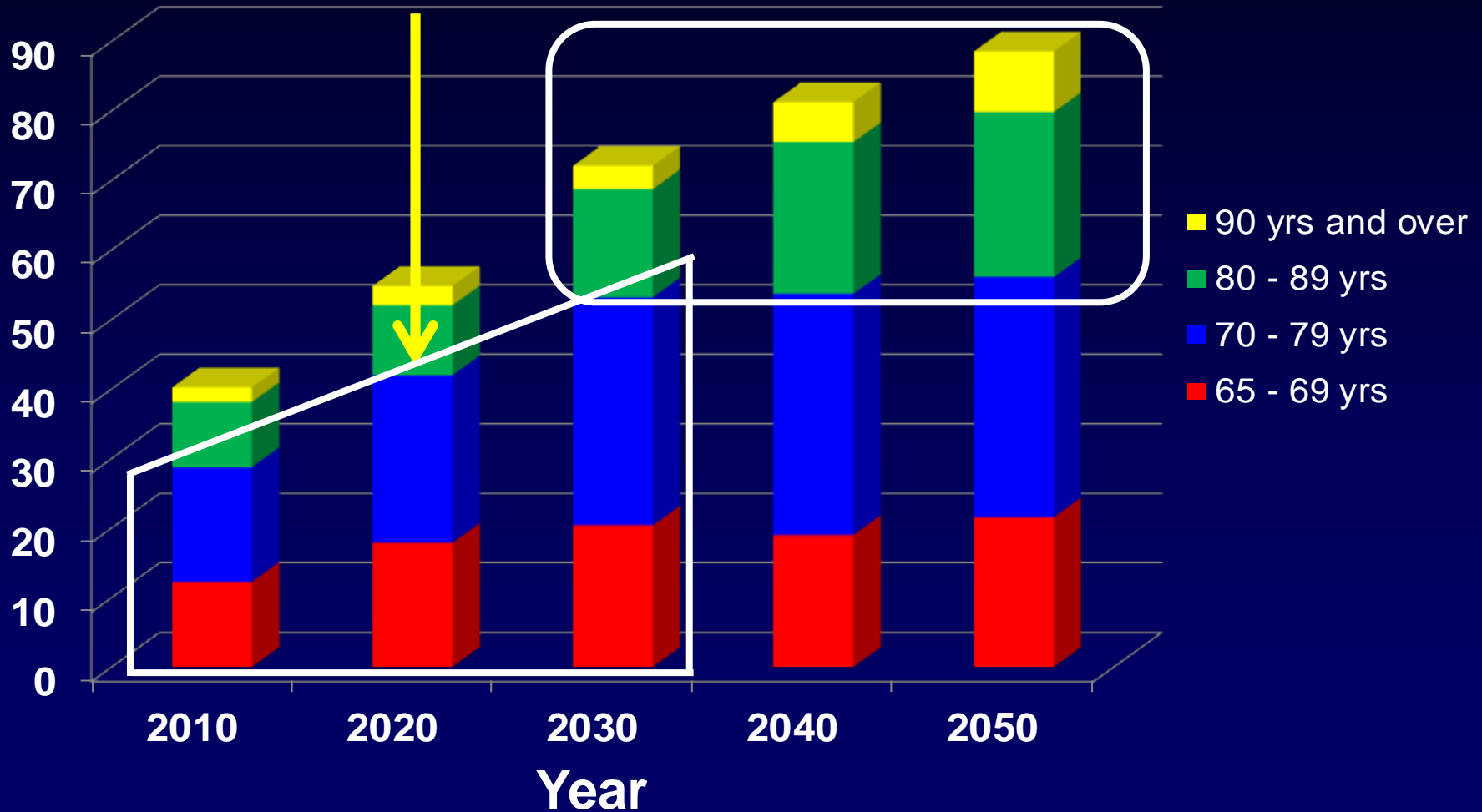
60% of cancer occurs in people \geq age 65



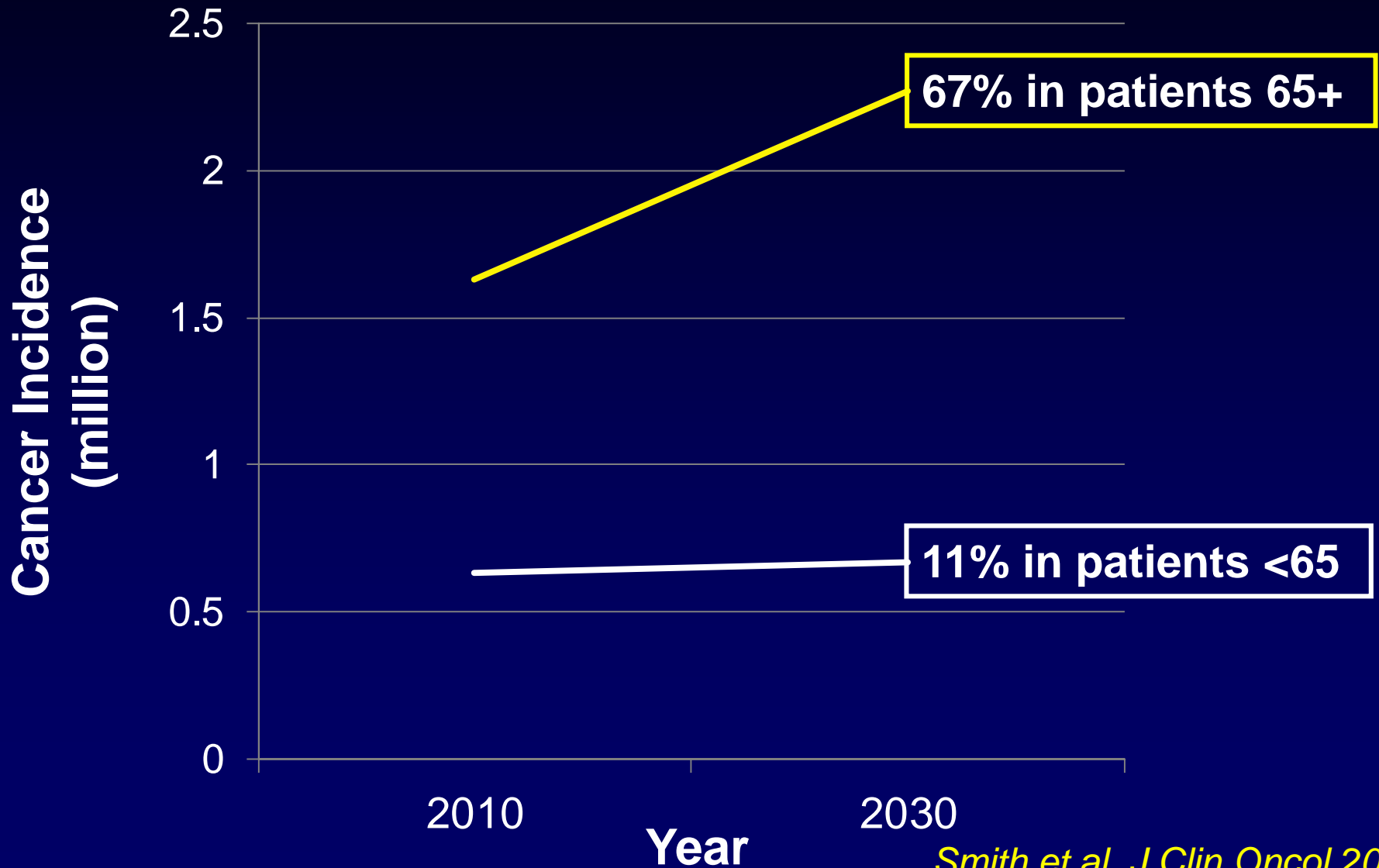
US Population Age ≥ 65 (millions)

2010 to 2030:
Largest growth in 65+ and 70+ age groups

Shift in 2030:
Largest growth in the 80+ age groups



Projected Rise in Cancer Incidence from 2010 to 2030



**Cancer is a Disease
Associated with Aging**

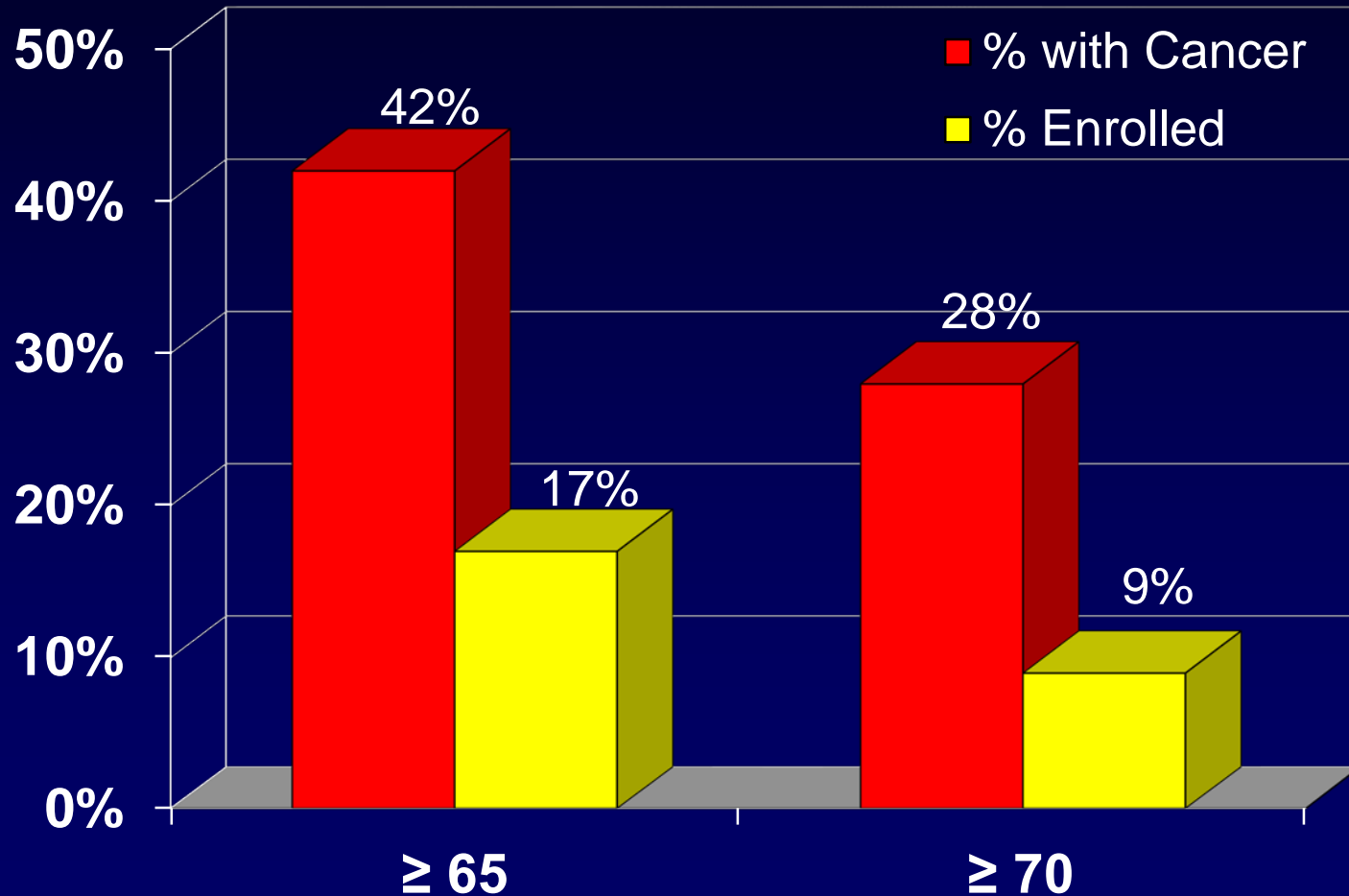
**The Number of Older Adults
is On the Rise**



Are We Prepared?

Older Adults Under-Represented on Cooperative Group Therapeutic Trials

Alliance Clinical Trials: 1985 - 2012



Few Older Adults Included in Registration Studies

Breast Cancer as an Example

Agent Name	Approval	N	Age ≥ 65	N	Age ≥ 75
Neratinib	7/2017	172	12%	25	<2%
Ribociclib	3/2017	150	45%	35	11%
Palbociclib	2/2015	181	41%	48	11%
		86	25%	27	8%
Ado-Trastuzumab Emtansine	2/2013	65	13%	11	2%
Everolimus	7/2012	290	40%	109	15%
Pertuzumab	6/2012	60	15%	5	1%
Eribulin Mesylate	11/2010	121	15%	17	2%
Lapatinib	1/2010	34	17%	2	1%
		282	44%	77	12%
Ixabepilone	10/2007	45	10%	3	<1%
		32	13%	6	2.5%

Package Insert, "Geriatric Usage" section

Pediatrics ≈ Geriatrics



Pediatrics

Geriatrics

Population Requires Unique Skill Set:

- Age-related change in physiology
- Vulnerable to toxicity
- Dependent in daily activities
- Concern regarding long-term effects of therapy

Aging is a Heterogeneous Process



Same Chronological Age; Different Functional Age

Hallmark of Aging: Decreased Physiologic Reserve

- Age-related change in organ function
- Increased # of comorbidities
- Increased risk of toxicity
 - Impact on cognition
 - Impact on function



Physiologic Reserve = Fuel Available

Integrating Geriatrics into Oncology

Factors other than chronological age that predict morbidity & mortality in older adults

- Functional status
- Comorbid medical conditions
- Nutritional status
- Cognition
- Psychological state
- Social support
- Medications (polypharmacy)

Geriatric
Assessment

What the “Typical” Patient Looks Like

- Needs assistance with daily activities
- Multiple comorbid medical conditions
- Mild cognitive impairment
- Limited social support
- Lives alone
- Transportation issues
- Polypharmacy
- Frailty



Likely Did Not Participate in the Registration Studies

Do We Address the Questions that Patients Want to Know?

Doctor, if I take the therapy...

- what is the quality of my survival?
- will I be functionally impaired?
- will I be cognitively impaired?
- what does my family need to prepare for?



Several Gaps in Knowledge

Multifaceted & Complex Problem: Multifaceted & Complex Solution

- The majority of individuals with cancer are older adults
- Older adults are under-represented on registration trials
 - Geriatric assessment not included
- There is a need to improve the evidence-base
 - Inform the Geriatric Use Subsection of the Package Insert

**Many possible solutions:
“What can I do to help?”**

Thank you!

