FDA-ASCO:
Geriatric Oncology Workshop

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Cancer is a Disease Associated with Aging

60% of cancer occurs in people ≥ age 65

CDC, Morbidity and Mortality Weekly Report 2013
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

2010 to 2030: Largest growth in 65+ and 70+ age groups
Shift in 2030: Largest growth in the 80+ age groups

U.S. Census Bureau 2010
Projected Rise in Cancer Incidence from 2010 to 2030

Cancer Incidence (million)

- 67% in patients 65+
- 11% in patients <65

Year

2010 2030

Smith et al, J Clin Oncol 2009
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

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

*Package Insert, “Geriatric Usage” section*
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)
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!