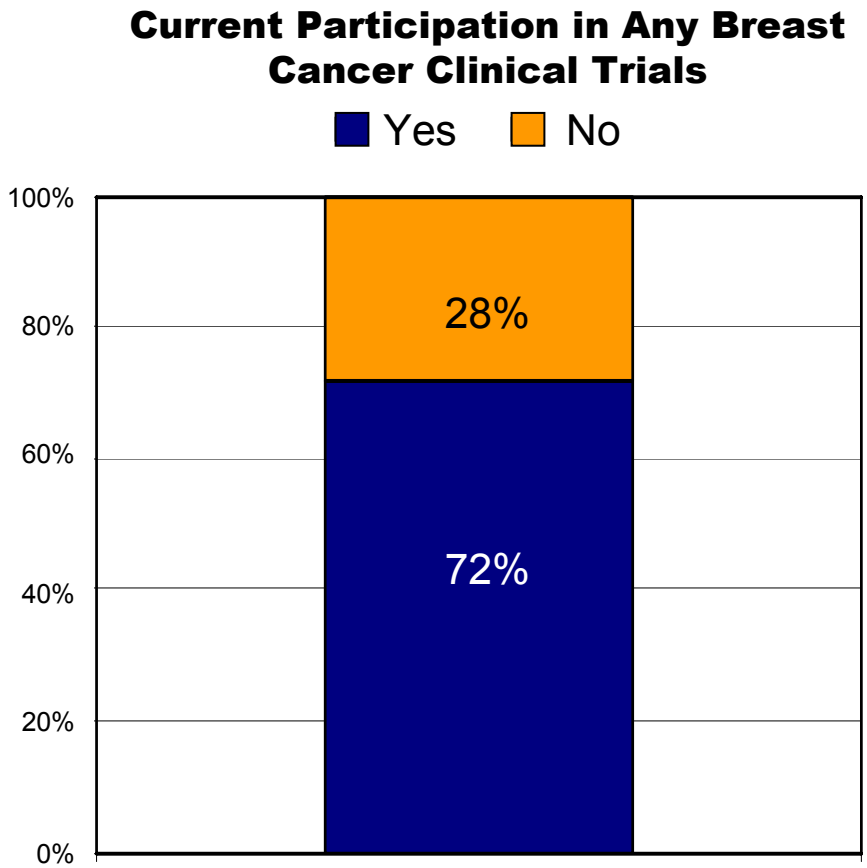
Clinical Trial Landscape in Breast Cancer – Activities and Challenges Now and in the Near Future

Source: **MDOUTLOOK March 2009 Global Survey of Physician Practices – "Current and Future Practices in Breast Cancer Management"**

Current Participation in Breast Cancer Clinical Trials is High



Key Conclusions

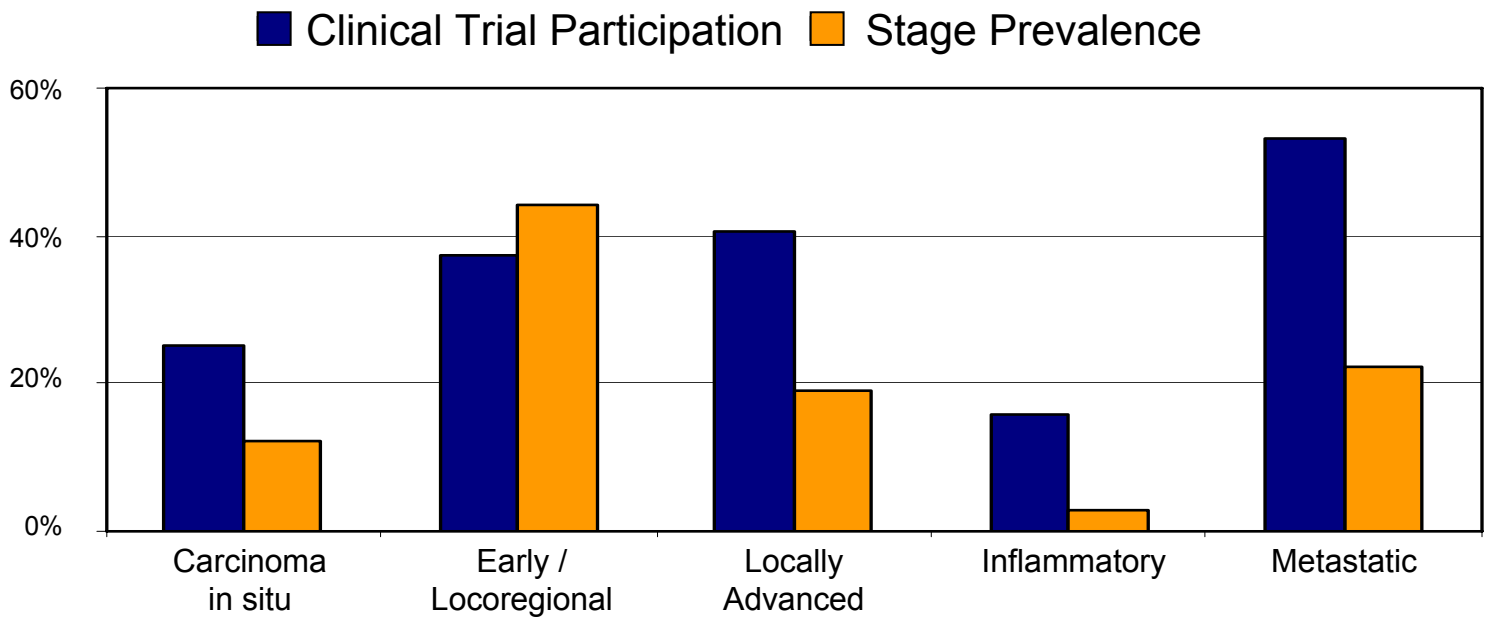
- High proportion of survey respondents are currently participating in clinical trial research
  - Information in this report is representative of this segment of the breast cancer community
- Respondents were from a sample across all disciplines, including group practices, community hospitals and academic centers

Additional Information

- "Current" is defined as having participated as an investigator within the past 2 years

Disproportional Relationship between Clinical Trial Participation and Disease Prevalence

Current Participation in Breast Cancer Clinical Trials by Stage



Key Conclusions

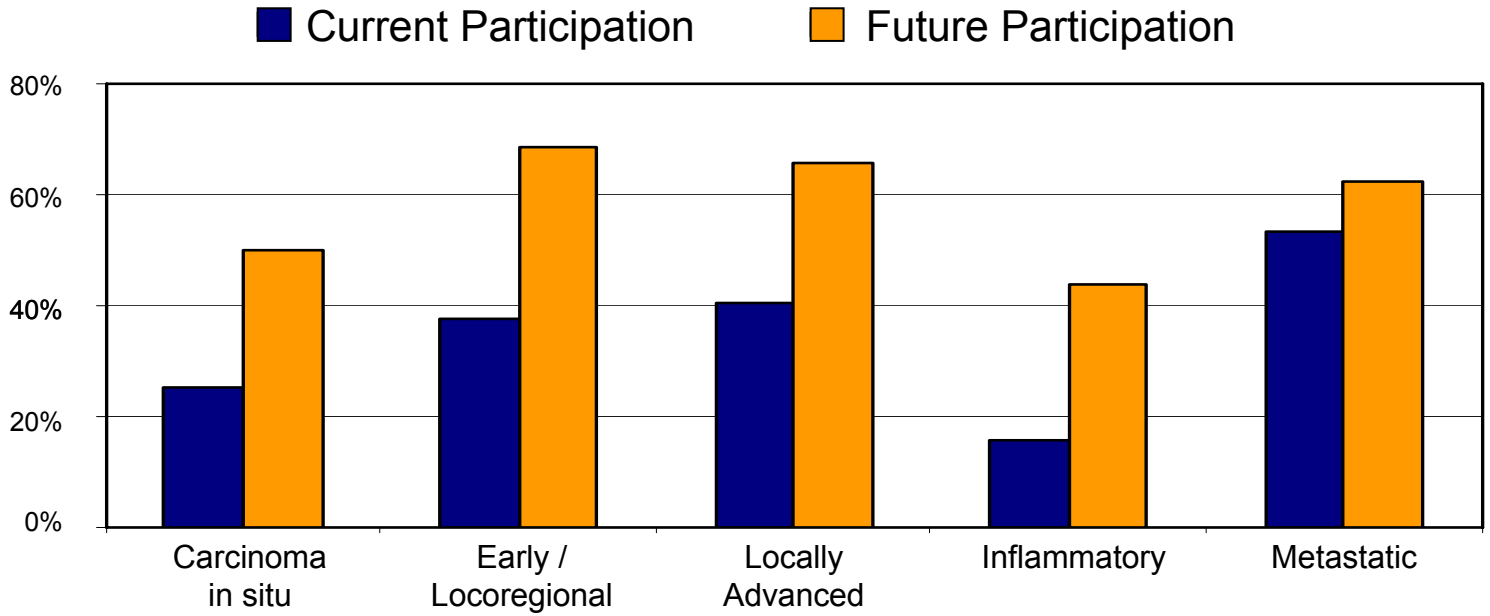
- Over 1/2 of survey respondents are involved in clinical trial research on metastatic breast cancer
- Discordance between physician involvement and patient population
  - Inflammatory breast cancer has the highest difference

Additional Information

- "Current" is defined as having participated as an investigator within the past 2 years
- Stage Prevalence determined from self-reported patient flow

Physician Interest in Clinical Trial Participation Extends Throughout Every Stage of Breast Cancer and Outpaces Current Participation

Desired Participation in Future Breast Cancer Clinical Trials by Stage



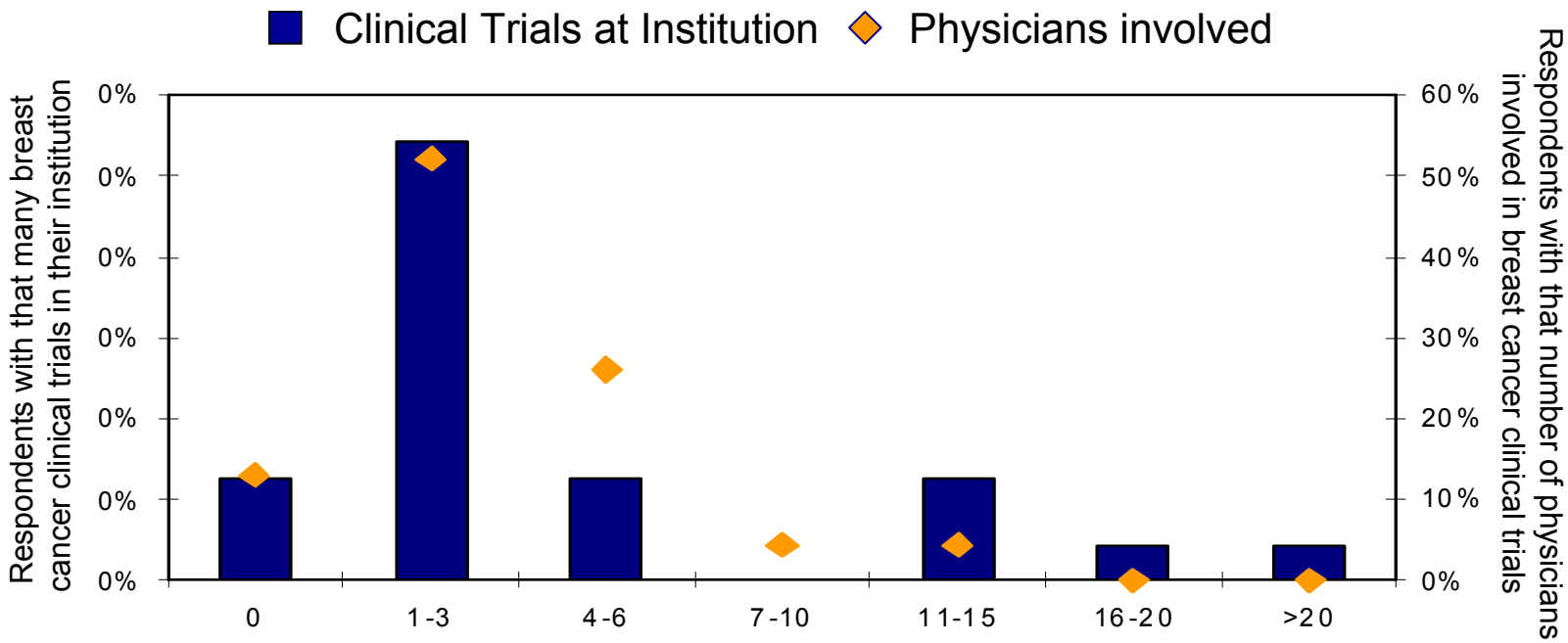
Key Conclusions

- Increased physician interest in clinical trial involvement for all disease stages
- Metastatic breast cancer has smallest difference between current and future
  - Saturation in participation levels?
- Desired interest significantly outpaces actual participation
  - Is there sufficient availability of suitable patients to feed adequate recruitment levels

Additional Information

- "Current" is defined as having participated as an investigator within the past 2 years
- "Future" is defined as within the next 2 years

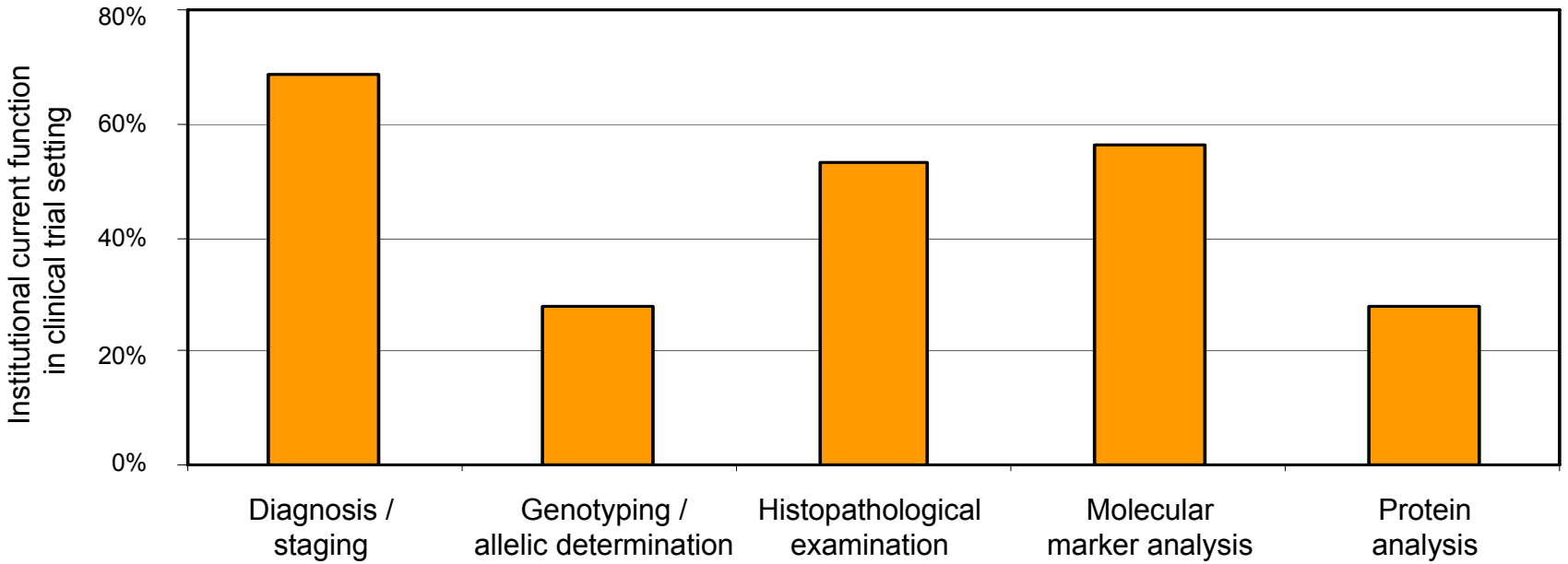
Institutional Involvement in Breast Cancer Clinical Trials



Key Conclusions

- Most institutions are participating in a select few clinical trials
- Only a small number of clinicians at these institutions are involved in the clinical trials
- About 20% of institutions are involved in a large number of clinical trials for breast cancer
  - Even at these “high-participation” institutions, only a limited number of physicians are involved in these clinical trials
- Is patient volume significantly large to ‘feed’ these trials?

Wide Variety of Laboratory Capabilities in Support of Clinical Trials



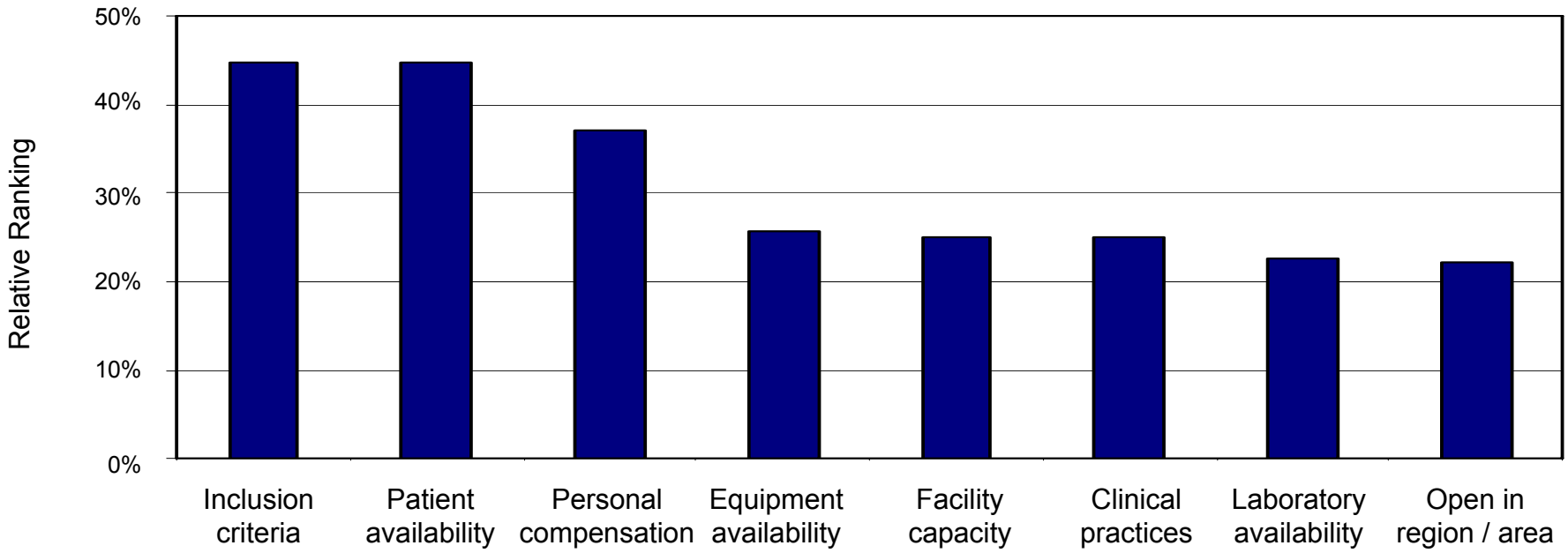
Key Conclusions

- No "universal" laboratory function available in-house
  - Diagnosis / staging was most prevalent at ~ 70%
- A central laboratory may be needed for genotyping and protein analysis within a clinical trial
- Every survey respondent's institution was performing some type of laboratory function for a clinical trial

Additional Information

- Data shown as a percentage of all survey respondents
- Respondents could select as many choices as applicable

Having the "Correct" Patients is the Biggest Challenge for Physicians to Participate in Clinical Trials



Key Conclusions

- The main factor preventing additional participation in clinical trials is having the patients available that fit the study's inclusion criteria
- Physician compensation is an important factor
- Institutional factors (equipment, capacity, laboratory, etc.) are NOT major detriments

Additional Information

- Each factor was ranked on importance by respondents
- Relative ranking calculated as the percentage of maximum score possible

Conclusions about Physician Involvement in Clinical Trials for Breast Cancer

- Nearly 3/4 of survey respondents are currently involved in clinical trial research for breast cancer
- For most stages of breast cancer, physician involvement in clinical trials is greater than what would be predicted from stage prevalence
  - Greatest physician involvement in studies for metastatic disease
  - Patient volume appears inadequate to feed current trial activity, especially in metastatic and inflammatory disease
- Significant interest in additional clinical trial participation across all stages of breast cancer
  - Metastatic disease may be nearing saturation
  - Is patient volume sufficient and adequate to feed future trial recruitment requirements?
- Most institutions run limited number of different clinical trials involving select faculty
- While ALL institutions have some capacity to provide laboratory support to clinical trials, no methodology in "universally" available
  - Use of central laboratories should be considered for genotyping and protein analysis within a clinical trial due to their limited availability
- Biggest challenge for physicians to participate in a breast cancer clinical trial is having the patient population that fits the study design
  - Physician compensation is an important driver to physician participation