



# Recruiting Patients for Cancer Trials: Focus on the Physicians!



Presentation by  
**Martin Lee, MD**  
Executive Vice President, Clinical Trial Services  
[mlee@davaonc.com](mailto:mlee@davaonc.com)

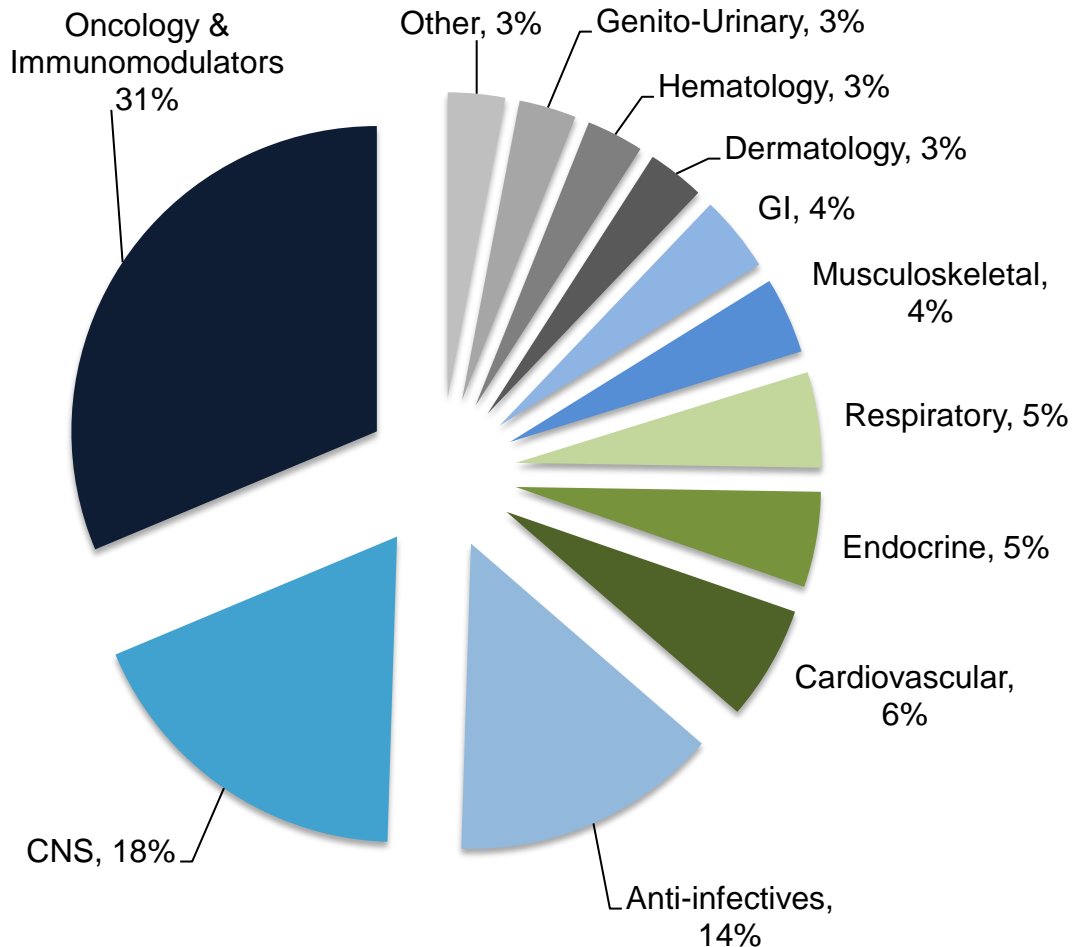


SCOPE Annual Meeting  
Wednesday, February 8, 2012



**DAVA**Oncology, LP  
...facilitating successful drug development<sup>SM</sup>

# Oncology is the largest therapeutic area in clinical research



**In 2010,  
31% of all compounds  
in clinical testing were  
oncology drugs or  
immunomodulators**

# Oncology trials currently utilize traditional recruitment techniques

## Accrual enhancement tactics:

- Informed consent aids
- Inclusion/Exclusion cards
- Pocket protocols
- Posters
- Brochures/Flyers
- Trial websites
- Internet-based recruitment
- Newsletters
- Journal advertisements
- TV advertisements

**Despite all the efforts, cancer clinical trial recruitment remains abysmal**

Why do these tactics work in other areas, but not for oncology?



# Cancer is different

## Cancer patients

- Cancer is a life-threatening illness
- Cancer diagnoses often result in fear, uncertainty, and has emotional impact
- Oncologists are important sources of psychological support for patients
- Unique relationship between oncologist and patient
- Shared decision-making
- Patients' unmet need is information

## Other therapeutic areas

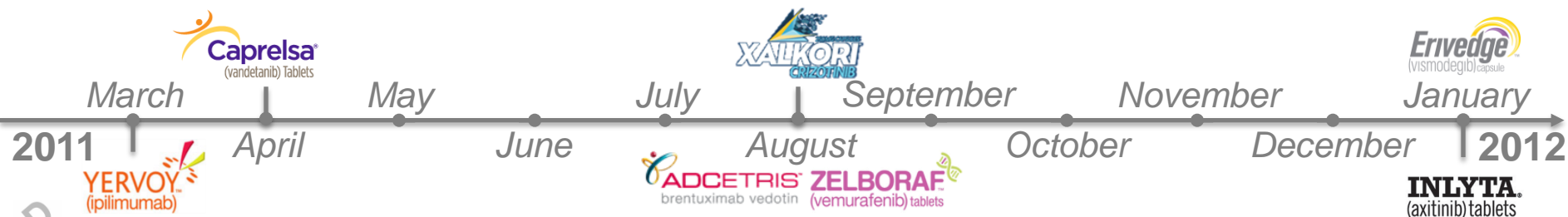
- May not be life-threatening
- Less emotional impact on patients
- Specialty physicians may not be involved
- Patients may make decisions without consulting with their physician
- Individual decision-making
- Information easily accessible for patients in various media outlets



# Cancer research is changing

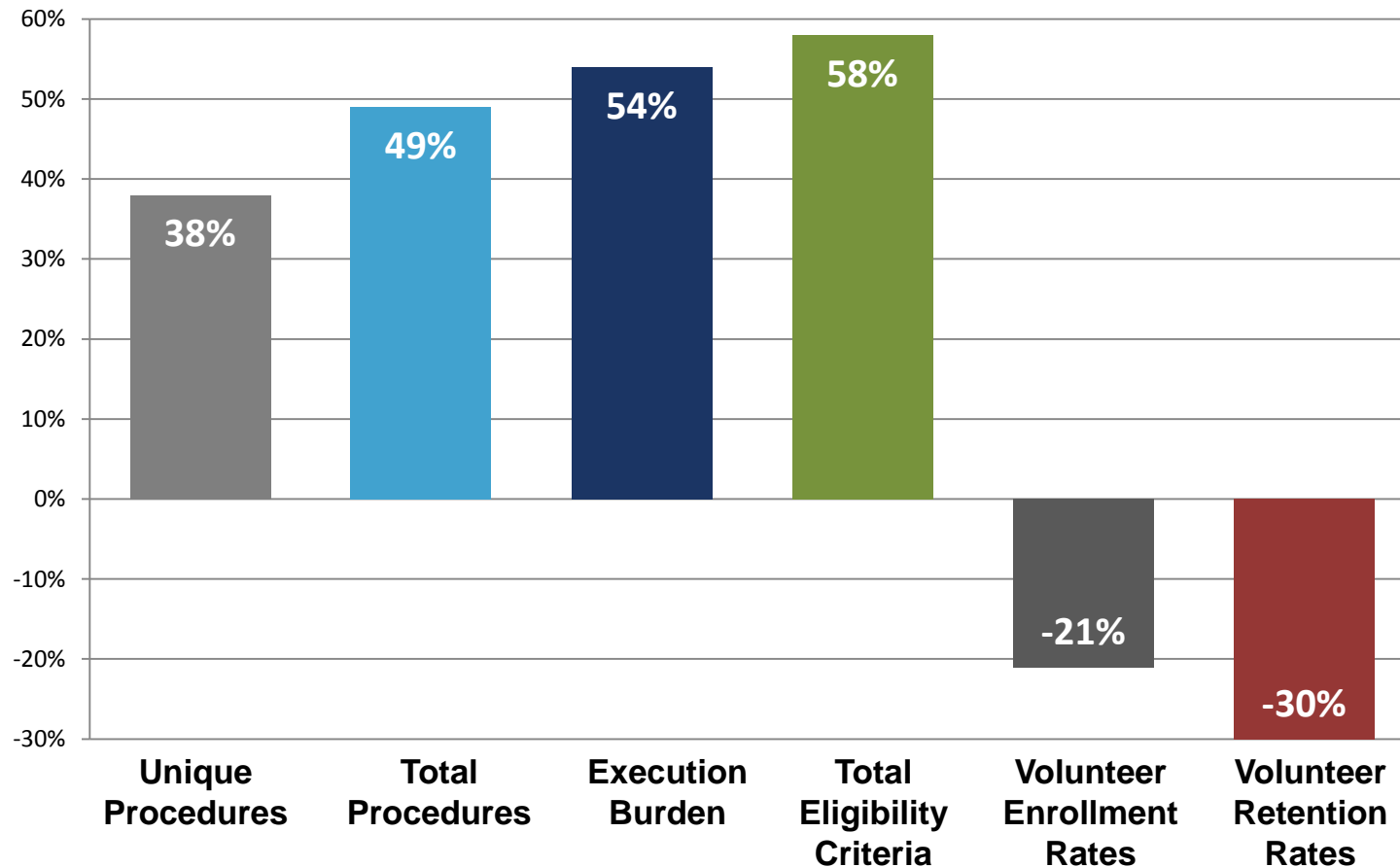
- **Targeted therapies are evolving**
  - Biomarkers are being identified
  - Screening for molecular targets is required before enrollment
  - Need for bio specimen donation by patients
- **Targeted therapeutics are gaining FDA approval**

Targeted therapeutics are gaining FDA approval



# Complexity is increasing

**Changes in Clinical Trials: Resources, Length and Participation**  
**Comparing 2000–2003 to 2004–2007**



# New specialties are involved in patient identification

Traditional approach

- **Oncologists and study coordinators** are the drivers of subject recruitment for clinical trials

- **Pathologists**
  - Early determination of subjects eligibility for clinical trials
  - Untapped potential for subject identification and referrals
- **Surgeons**
  - Highly involved in trials with a surgical component
- **Radiologists**
  - Interventional radiology Involved in obtaining tissue for biomarkers
- **Referral Medical Oncologist**
  - Increased awareness results in more referrals

New specialties involved



# A new approach: Focus on the Physicians!

- **Physician education is key to accrual**
  - Continued medical oncologist education and engagement through peer to peer interactions proven to increase enrollment
- **Frequent interactions with physicians to:**
  - Discuss patient eligibility issues in cooperation with the medical monitor
  - Quickly resolve eligibility queries
  - Identify and discuss opportunities to accelerate accrual at the site
  - Share best practices
  - Keep sites informed about accrual status
  - Discuss other trial issues at the site
  - Review data presented in public forums and in public sources of new and emerging trials and drug data of interest which could affect trial accrual



# A new approach: Focus on the Physicians!

- **Pathologist, surgeon & referral physician interactions**

- Expand outreach, education & engagement of key stakeholders
- Pathologist, surgeon & referral physician are becoming key players in patient identification

- **Accrual Visits**

- Face to face meetings with physicians to deliver protocol key messages

- **Accrual Workshops**

- Small, interactive meetings to educate investigators through case-based learning activities



# Case-based learning

Recruitment

Scientific Story

Strategies

12:00 p.m. – 12:30 p.m.	<b>Lunch</b> Networking time	
12:30 p.m. – 1:00 p.m.	<b>Introductions:</b> Welcome Goals and Objectives Site introductions and overview	<i>DAVA MD</i>
1:00 p.m. – 1:20 p.m.	<b>Overview of Her-2 Positive MBC:</b> Choice of chemotherapy Unmet clinical needs	<i>Investigator</i>
1:20 p.m. – 2:20 p.m.	<b>Advancing HER-2 blockade in MBC</b> Protocol rationale Clinical trial issues (eligibility, imaging, etc.) Adverse event management	<i>Company MD/Clinical Ops</i>
2:20 p.m. – 2:35 p.m.	<b>Break</b> With refreshments	
2:35 p.m. - 4:30 p.m.	<b>Case Presentations and Discussions:</b> Discussion of cases related to appropriate patient selection, enrollment challenges, adverse event management and any other issues	
4:30 p.m. – 5:00 p.m.	<b>Strategies to Accelerate Accrual:</b> Communicating with potential referring physicians New ideas, learning, sharing of best practices and take away points	

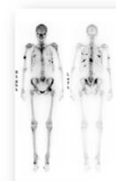
## Agenda

### Case Study

Case #3: 70W with ER-/HER-2+ MBC progressing after trastuzumab

- History**
- 70 yr women initially presented with a positive mammogram
  - Biopsy demonstrated ER-/HER-2 Positive IDC
  - MRM on 6/17/06 demonstrated a 3.5 cm mass with 3/12 + LN
  - Treated with TCH x 6 then 1 year of trastuzumab ending 7/07

- Recurrence**
- On 10/08 she developed pain in the back. Bone scan demonstrated wildly metastatic disease with biopsy confirming HER-2 + MBC.
  - Treated with 10 cycles of paclitaxel and trastuzumab then developed increase RUQ pain and CT demonstrated new liver metastasis.

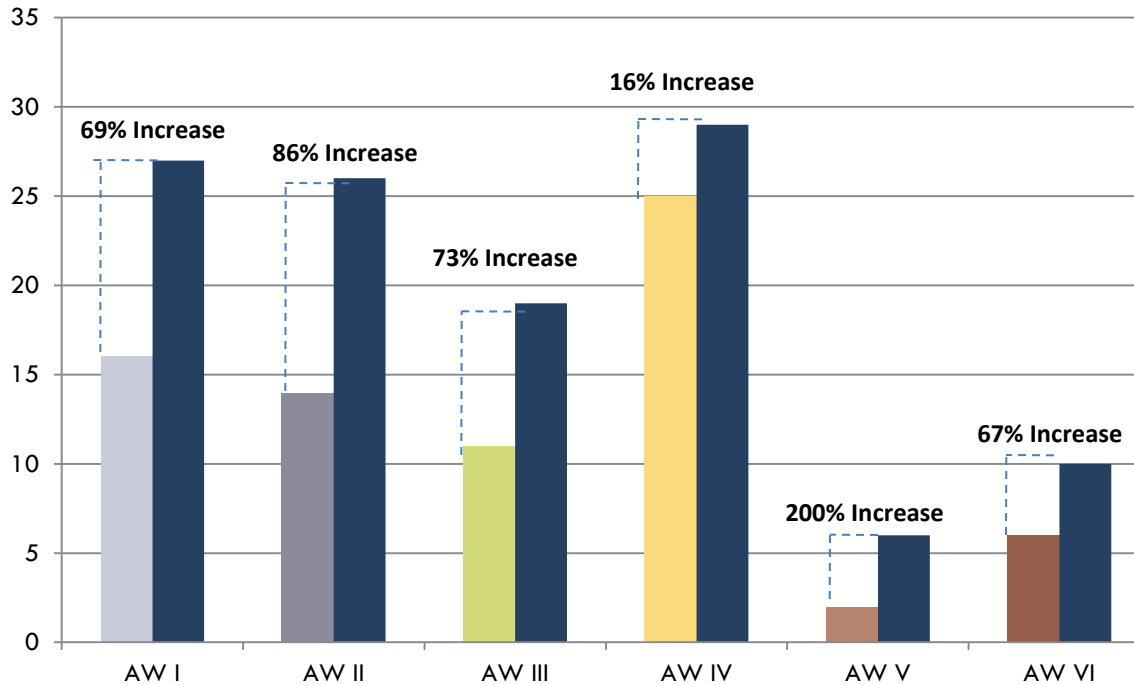


- Would you continue trastuzumab and change the chemotherapy?
- For this patient, when would you discuss the study trial?

## Case Studies



# Accrual Workshop impact

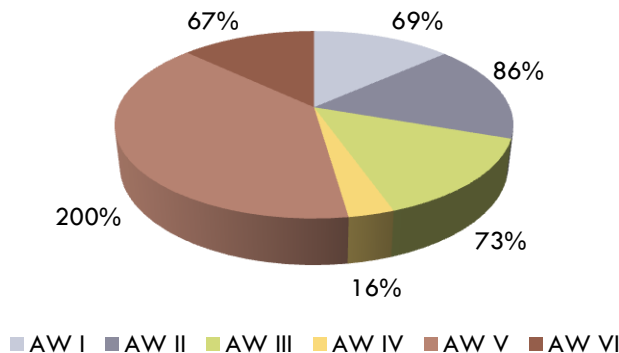


**85% Cumulative Accrual Increase**

**6 AWs in multi-center phase III trial**

- Dallas, TX – 15 sites
- Boston, MA – 15 sites
- Philadelphia, PA – 11 sites
- Los Angeles, CA – 21 sites
- Chicago, IL – 6 sites
- New York, NY - 13 sites

**120 day accrual pre-AW vs. post-AW**



**○ Average of 20 pts accrued after each workshop vs. 12 pts before workshop**



# Overall interaction summary

Site Interactions	
<b>TOTAL # OF INTERACTIONS</b>	<b>970</b>
<b>Site Engagement</b>	
MD Interactions	<b>226</b>
CTS Interactions	<b>642</b>
Site Visits	<b>3</b>
<b>Accrual Enhancement</b>	
MD Interactions	<b>34</b>
CTS Interactions	<b>51</b>
Accrual Visits	<b>3</b>
Accrual Workshop Attendees	<b>11</b>

**2 Investigator Meetings**  
San Diego, CA  
Miami, FL



**462 MD and CTS**  
**Phone**  
**Interactions**



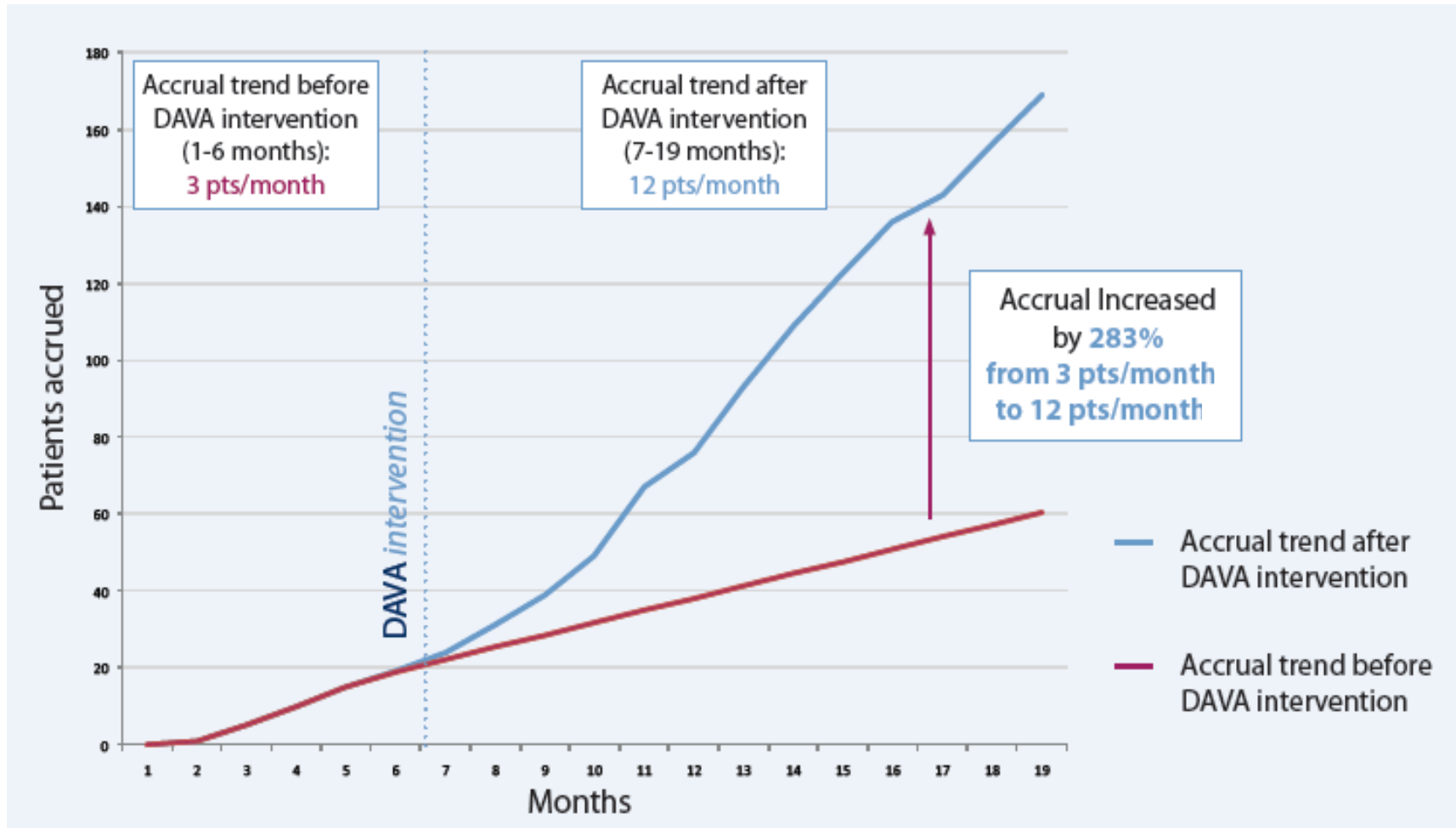
**ASH Orlando**  
**Accrual Workshop**  
**9 MDs, 2 research staff**

DAVA Site Visits



**6 Accrual Visits**

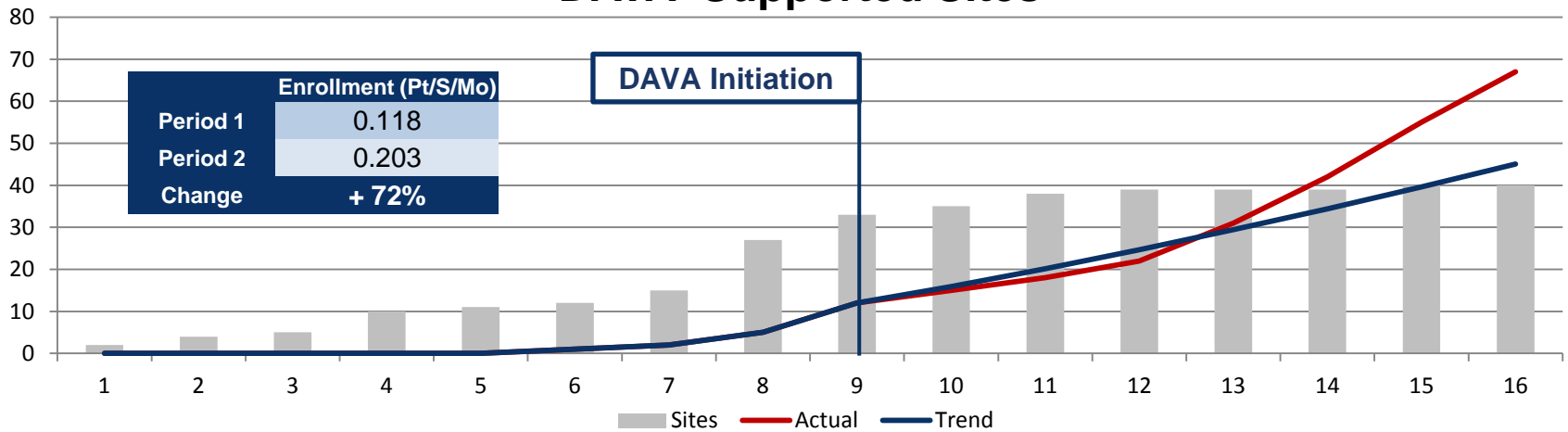
# Overall impact of physician education & engagement



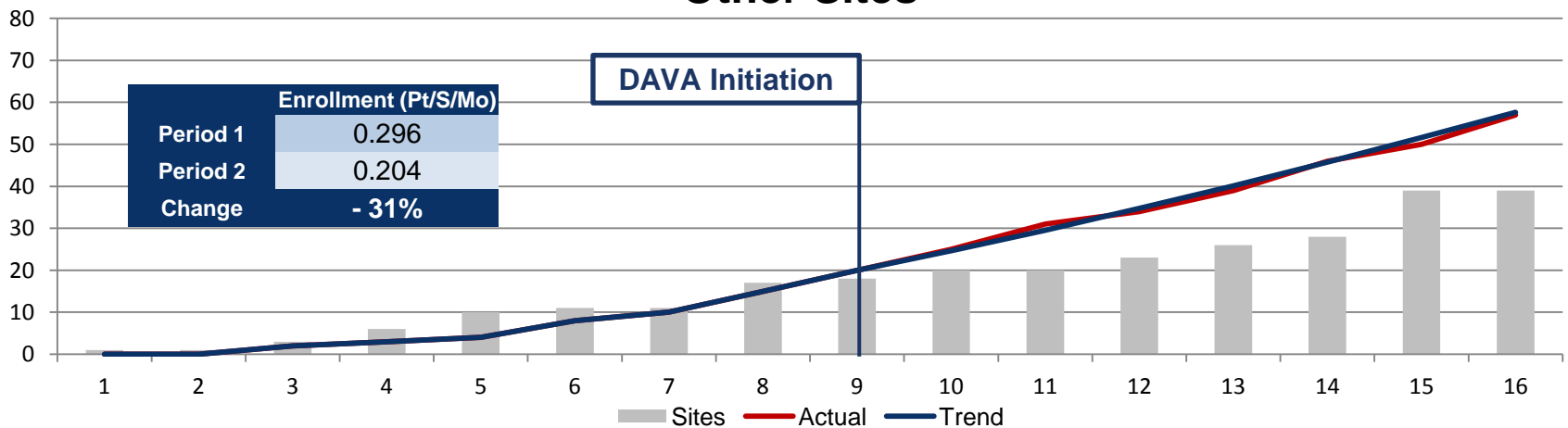
Source: DAVA Oncology. Impact of direct physician-to-physician contact on accelerating oncology clinical trial accrual in multiple tumor types. Poster presentation at ASCO 2011

# Trial specific impact of physician education & engagement

## DAVA Supported Sites



## Other Sites





# Thank you for your participation!

If you have any questions, please contact me!

**Martin Lee, MD**

Executive Vice President, Clinical Trial Services

214.451.4533

mlee@davaonc.com

[www.davaonc.com](http://www.davaonc.com)



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