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# Private Sector: The Imperative of Metrics

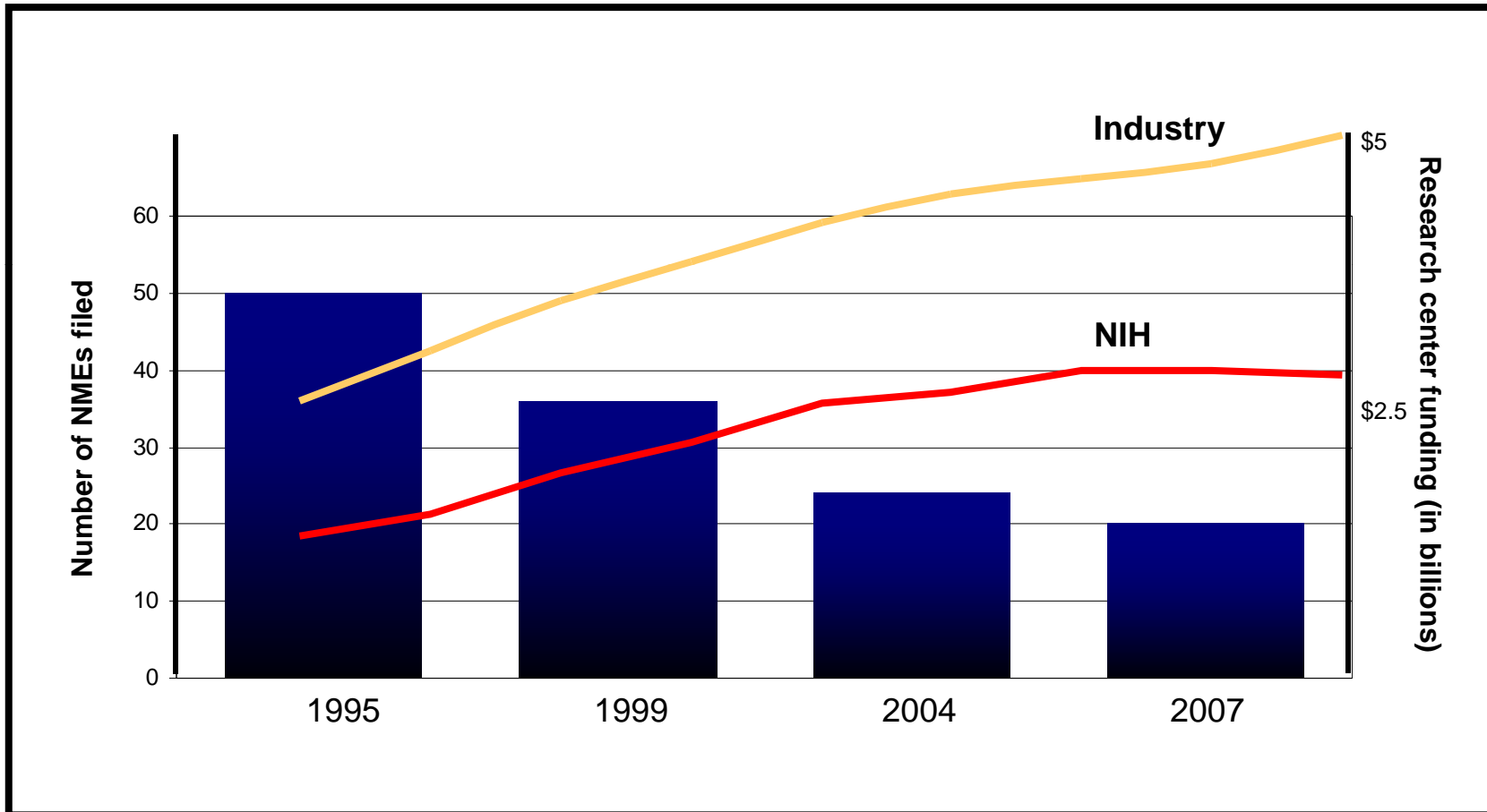
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## **2nd Annual CTSA Clinical Research Management Workshop**

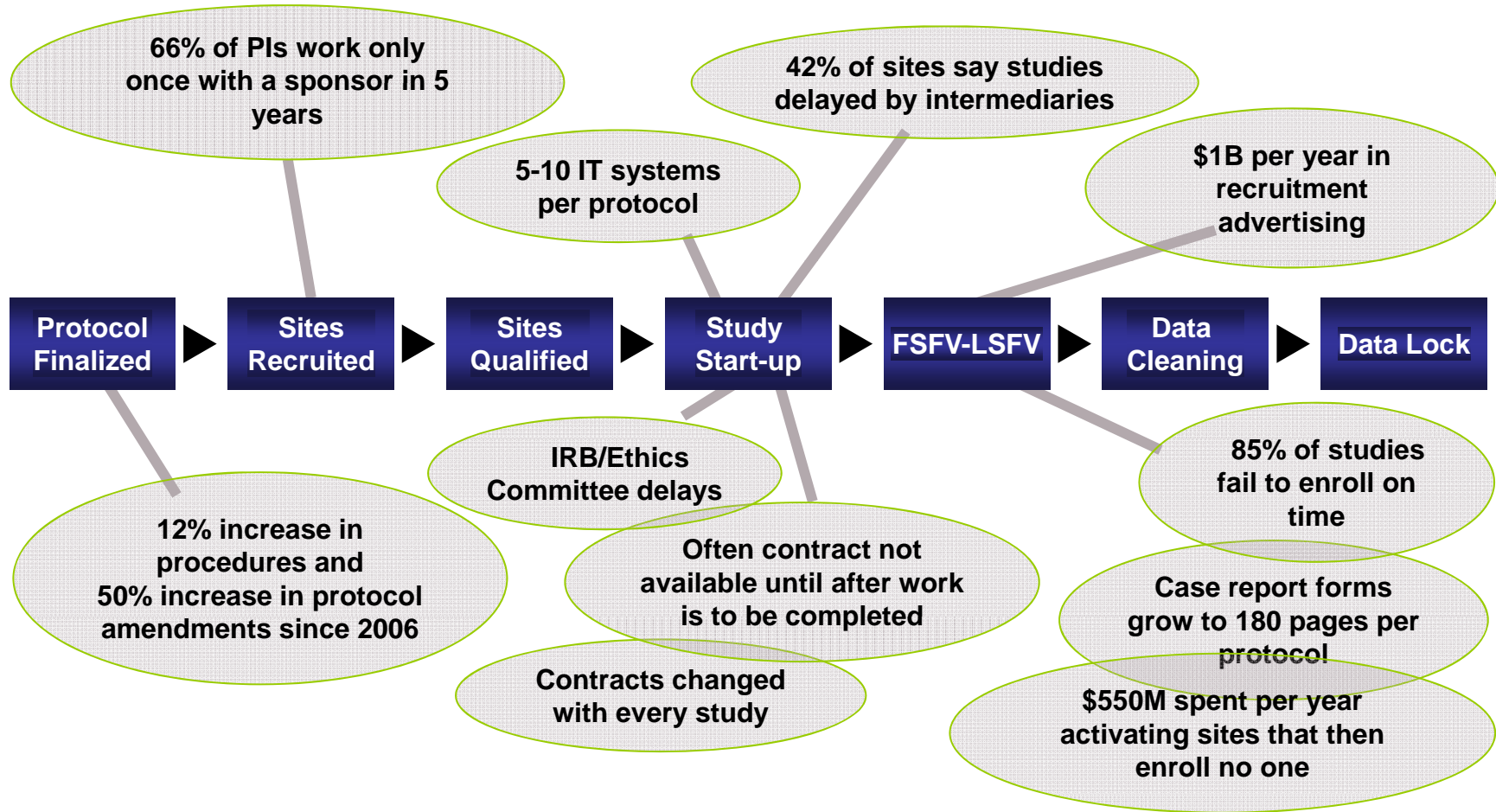
**Tracy Harmon Blumenfeld  
Chief Executive Officer**

**June 23, 2009**

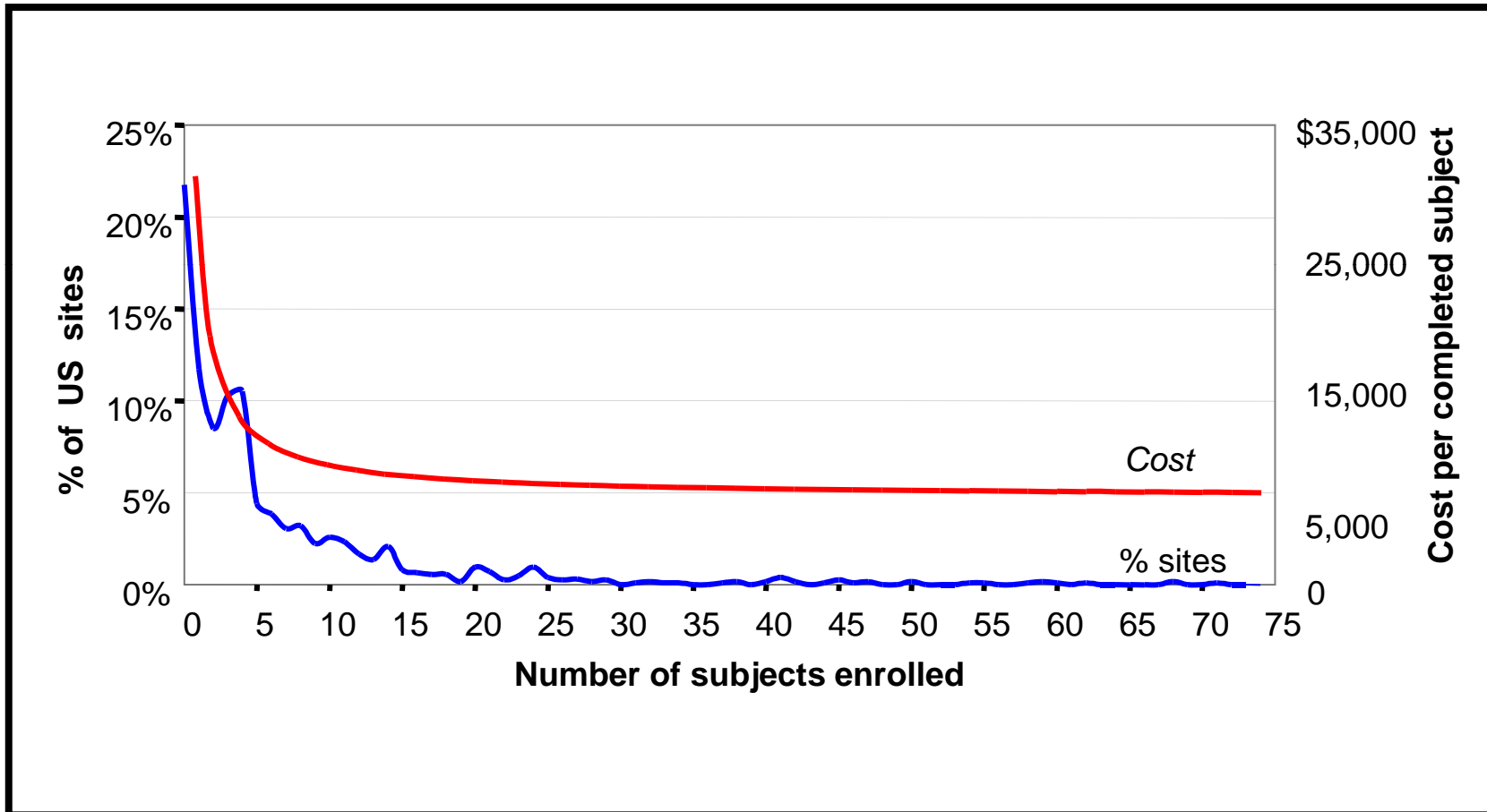
# More Expense, Fewer Treatments



# Productivity Breakdown



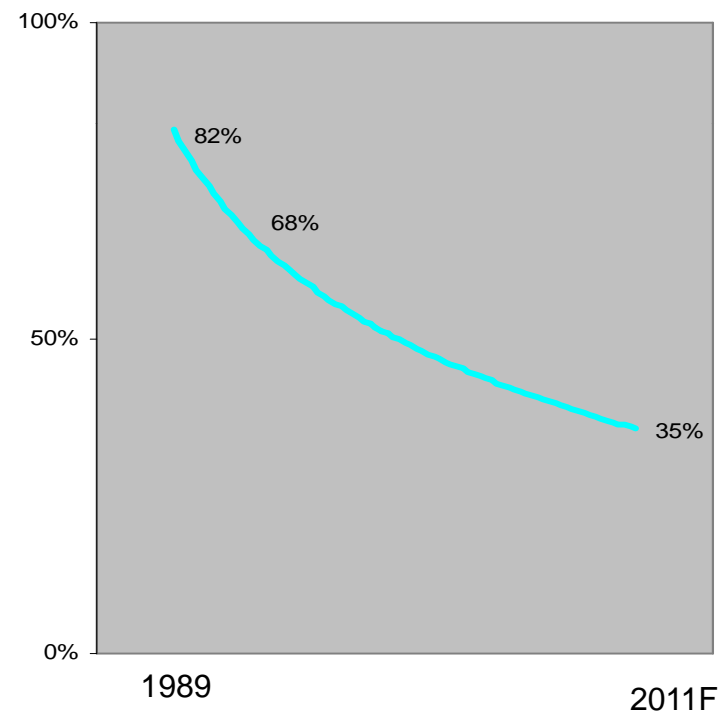
# Industry Focus: Select the High-Performing Sites



# More Competition for a Slice of a Shrinking Pie...

- On average 15% of total AMC revenues comes from participating in industry sponsored clinical trials <sup>(1)</sup>
- Academic medical centers face increased competition from:
  - Other academic centers
  - Community based sites
  - Dedicated research centers
  - Other countries

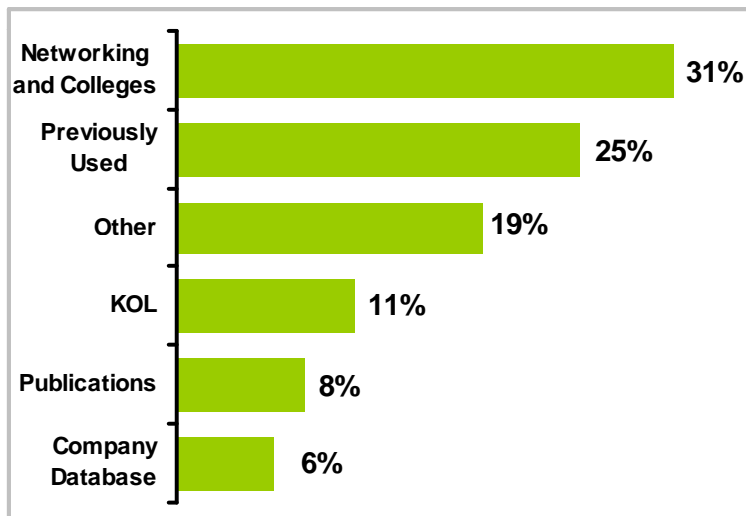
Declining Share of Market for AMCs  
(1989-2011)



- (1) [Joshua B. Powers - Buying In or Selling Out?: The ...](#)  
**Buying In or Selling Out? The Commercialization of the American** Research University. Piscataway, NJ: Rutgers University Press, 2004.
- (2) Kongstvedt, Peter Reid, **managed health care handbook; Tufts Outlook**

# A Shift Toward Metrics

## Relationships that drove site selection ...



## ... will now compete with data

- Select geographic regions and countries
- Generate site lists
- Eliminate low- or non-performing sites before reaching out to prospective PIs

# What Industry Watches ... and Why

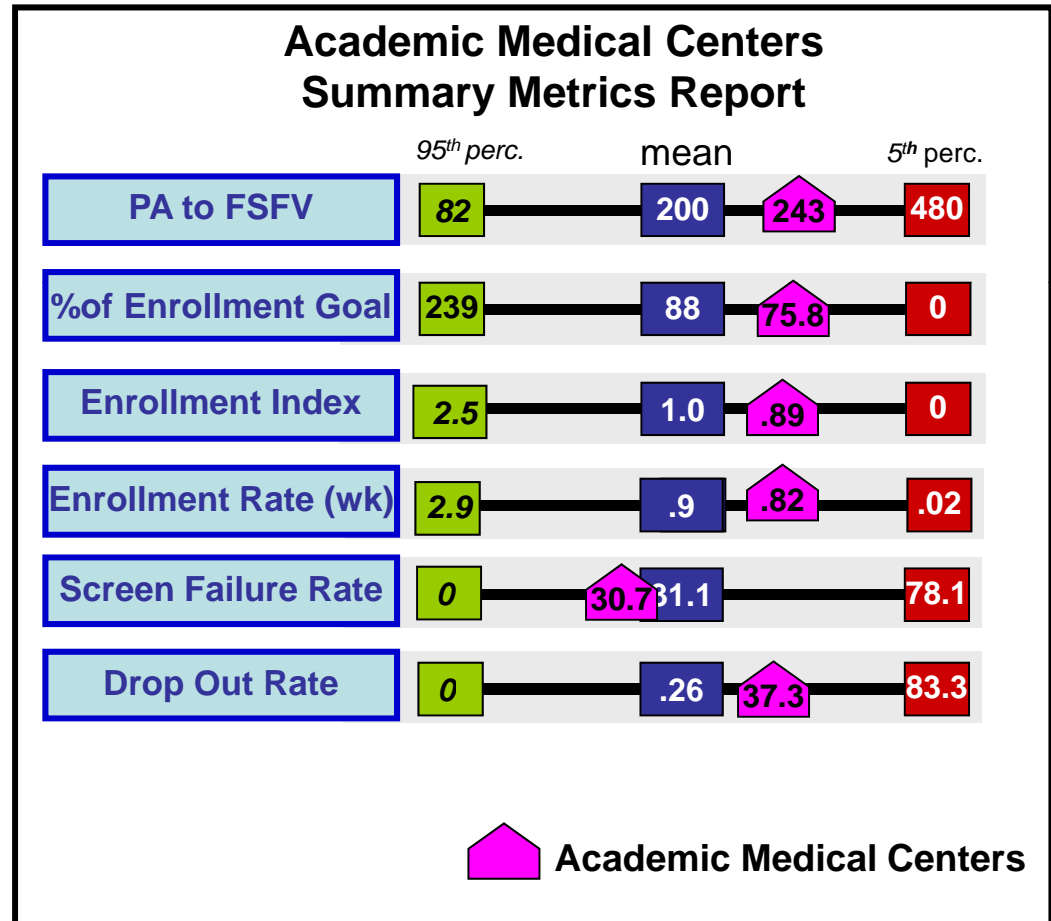
<b>Metric</b>	<b>Definition</b>	<b>Trend</b>
Protocol Approval to First Subject First Visit	Protocol approval date to date of first subject first visit. (PA to FSFV)	↑ 74%*
Enrollment Index	Subjects enrolled divided by number of contracted subjects	↓ 33%
Enrollment Rate	Subjects enrolled divided by enrollment period	↑ 16 %
Screen-Failure Rate	Subjects completing screening visit minus number of subjects enrolled divided by number of subjects completed screening visit	↑ 64%
Drop-Out Rate	Subjects completed minus subjects enrolled divided by number of subjects enrolled	↑ 68%

# Data Sources

Level	#	Description
Companies	5	Top-10 pharmaceutical companies (\$ R&D)
Protocols	438	Phases II-IV, Conducted 1997-2008
		Phase II 32.9% Phase III 54.7 % Phase IV 12.4%
Compounds	121	10 Therapeutic areas
Unique principal investigators	7,049	Academic, Veterans Affairs/Military, Dedicated Research Center, and Other/Community
Sites (PI/protocol pairs)	14,857	U.S. sites only, representing all 50 states, the District of Columbia, and Puerto Rico
Subjects	91,783	Enrolled subjects

# Scorecard: Academic Centers

- Study initiation at academic centers is 43 days longer than at professional and community sites
- Delayed start-up puts academic medical centers at an enrollment disadvantage
- Once up and running, academic sites are roughly 10% slower in enrollment than dedicated and professional sites
- Academic centers are better at screening appropriate patients but retain fewer



# Why Academic Centers Are Less Productive...



## Academic Physicians

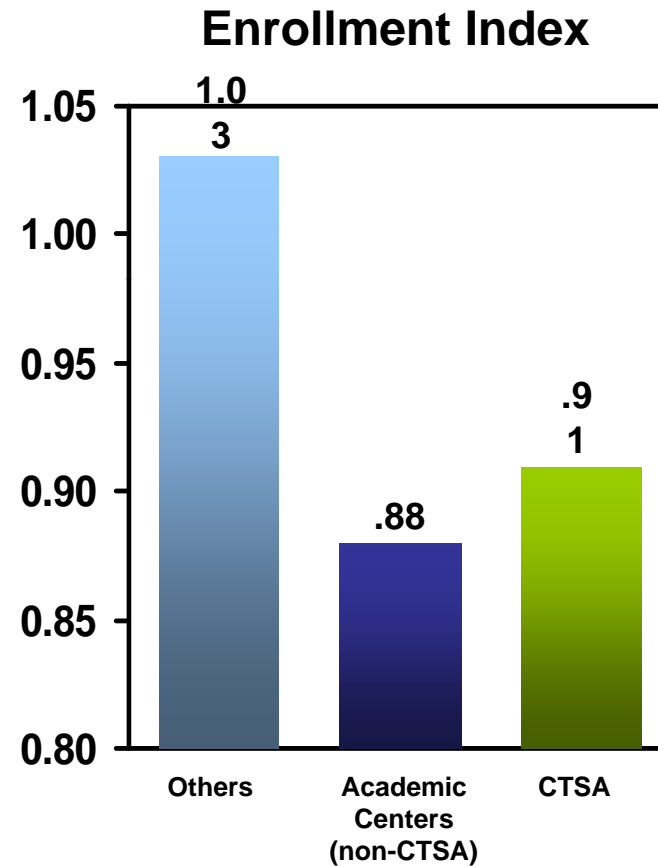
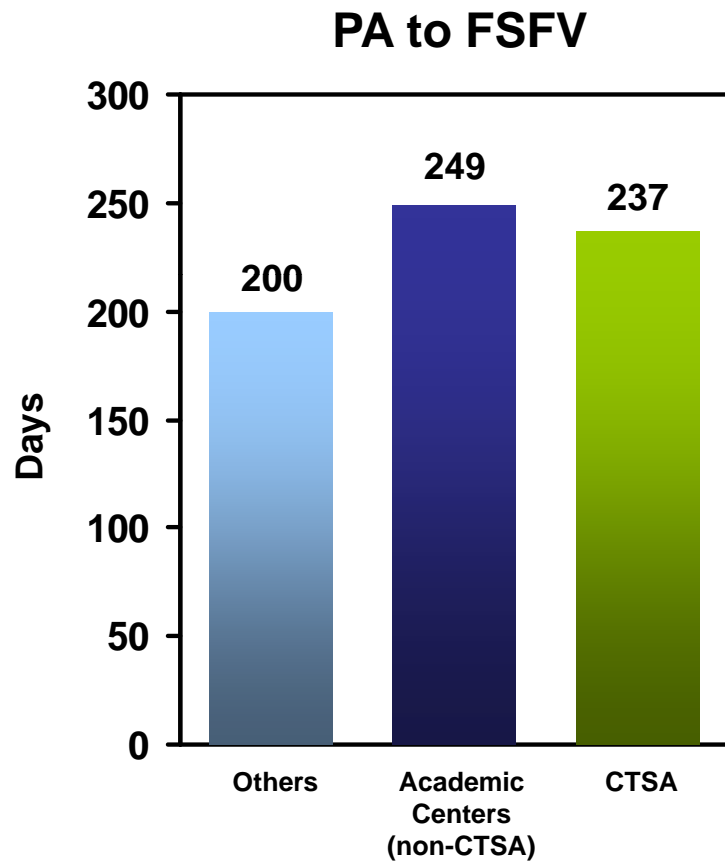
- Few if any financial incentives tied to enrollment
- Publication important but not linked to trial performance
- Coordinators often assigned by project



## Community Physicians

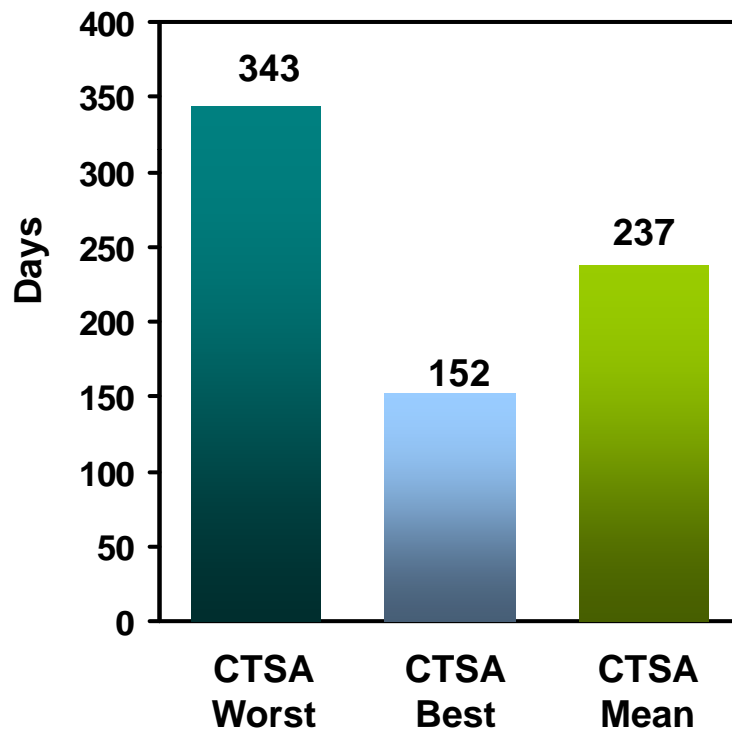
- Clear financial incentives tied to enrollment
- Publication relatively less important
- Coordinator-investigator teams relatively constant

# Scorecard: CTSA Members



# Leveraging Variability To Drive Higher Performance

**PA to FPFV  
CTSA Members**



**Potential Explanations  
Of Variance**

- **Process, systems and workflow**
- **Allocation of accountability (PI vs. central office)**
- **Availability of resources**
- **Training and support**
- **Motivation and commitment**
- **Importance of industry-funded research as a funding source**
- **Infrastructure supporting IRBs and contracting**

# Recommendations

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- Understand your current competitive position
- Know your capabilities before agreeing to participate
- Forecast, plan, then pressure-test
- Measure, benchmark and course-correct

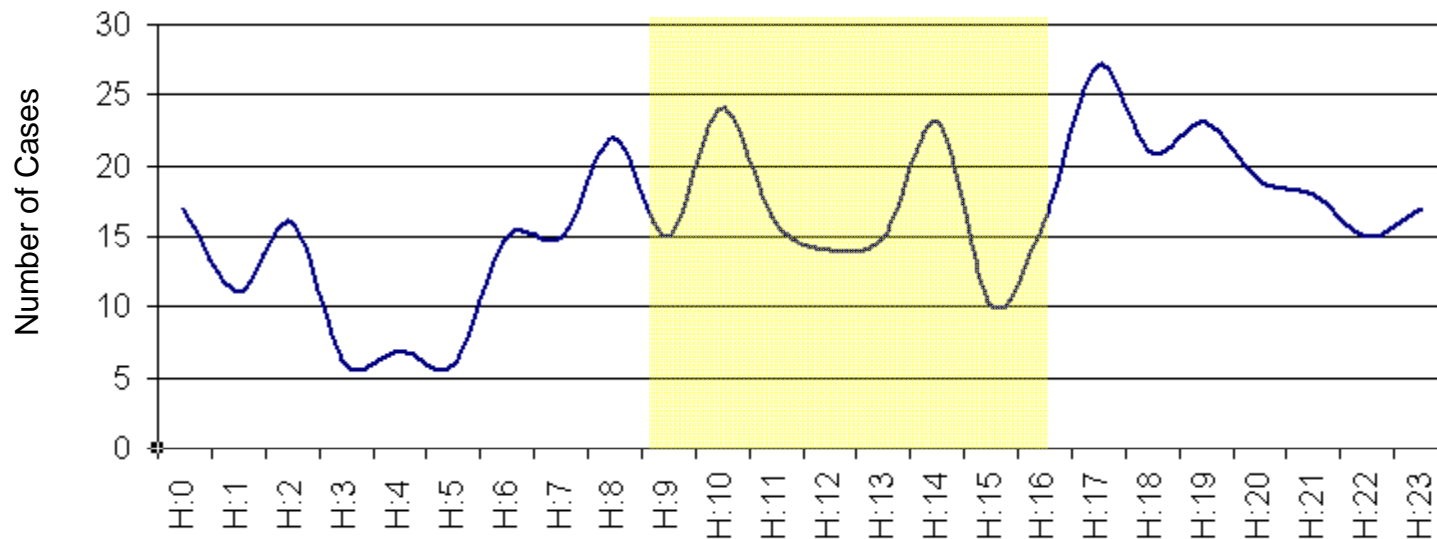
# Understand Your Competitive Position


CTSA Member Profile		
Therapeutic Area	#	
Respiratory	10	
Neurology/CNS	7	
Metabolism	6	
Infectious Disease	5	
Cardiovascular	5	
Oncology	4	
Other	2	
Musculoskeletal/ Rheumatology	1	
Total	40	
<b>Unique Investigators</b>	<b>25</b>	
Pharmaceutical Company	# of Trials	% Goal Met, Ave.
Company I	4	62.5%
Company II	5	94.7%
Company III	31	93.3%

Relative Performance Of CTSA Member		
	PI Protocol Pairs	% of PIs > Trial's Mean Enrollment
CTSA Member	40	40.0%
All Academic	2860	41.9%
Non-Academic	9028	48.9%
	PA to FSFV	% of Sites With 0 enrolled
CTSA Member	270.1	10.0%
All Academic	140.8	8.3%
Non-Academic	97.9	6.2%

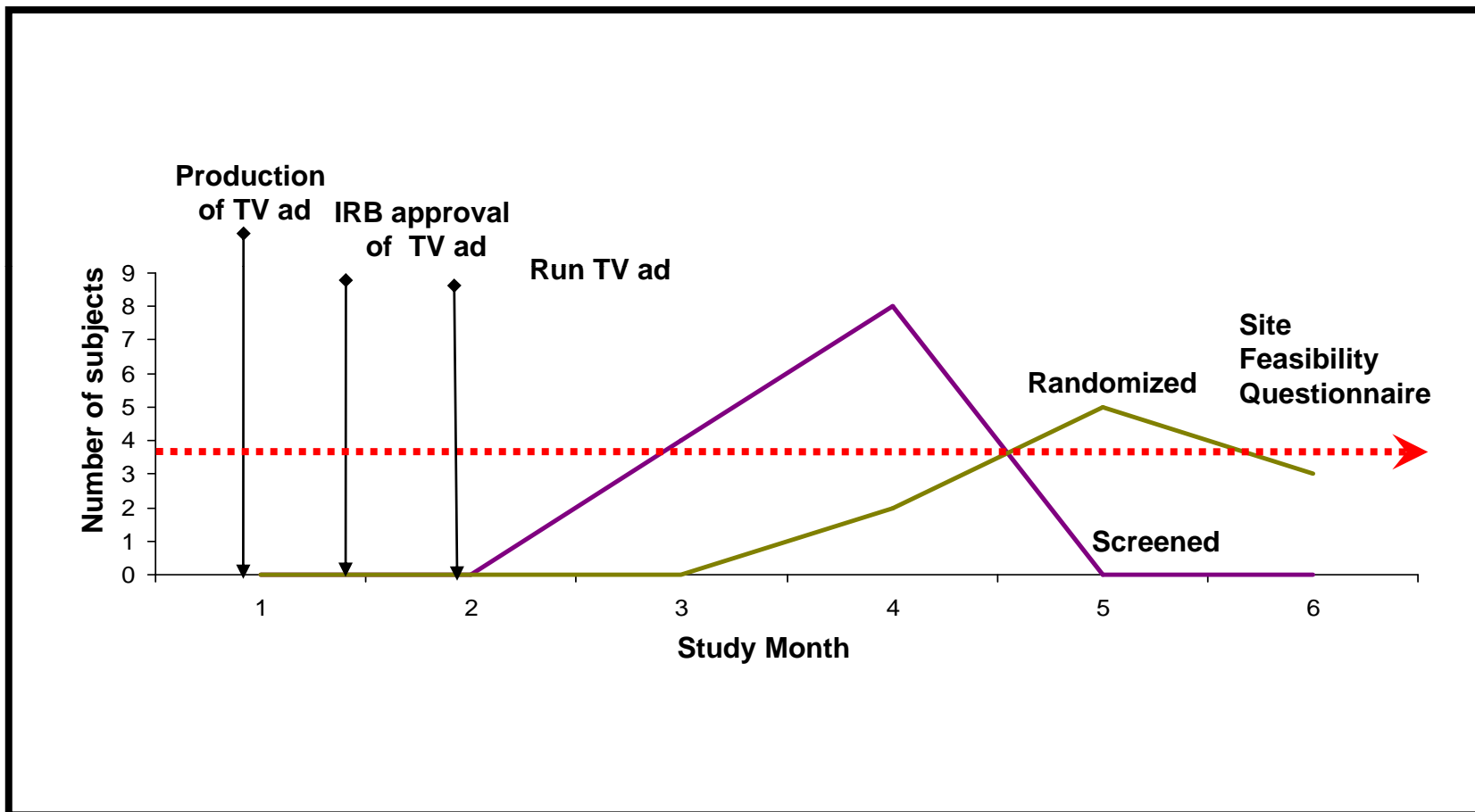
# Know Your Capabilities

**Emergency Department Utilization  
Mean Number of Acute Asthma Attack Cases  
By Time of Day (trailing 12 months)**

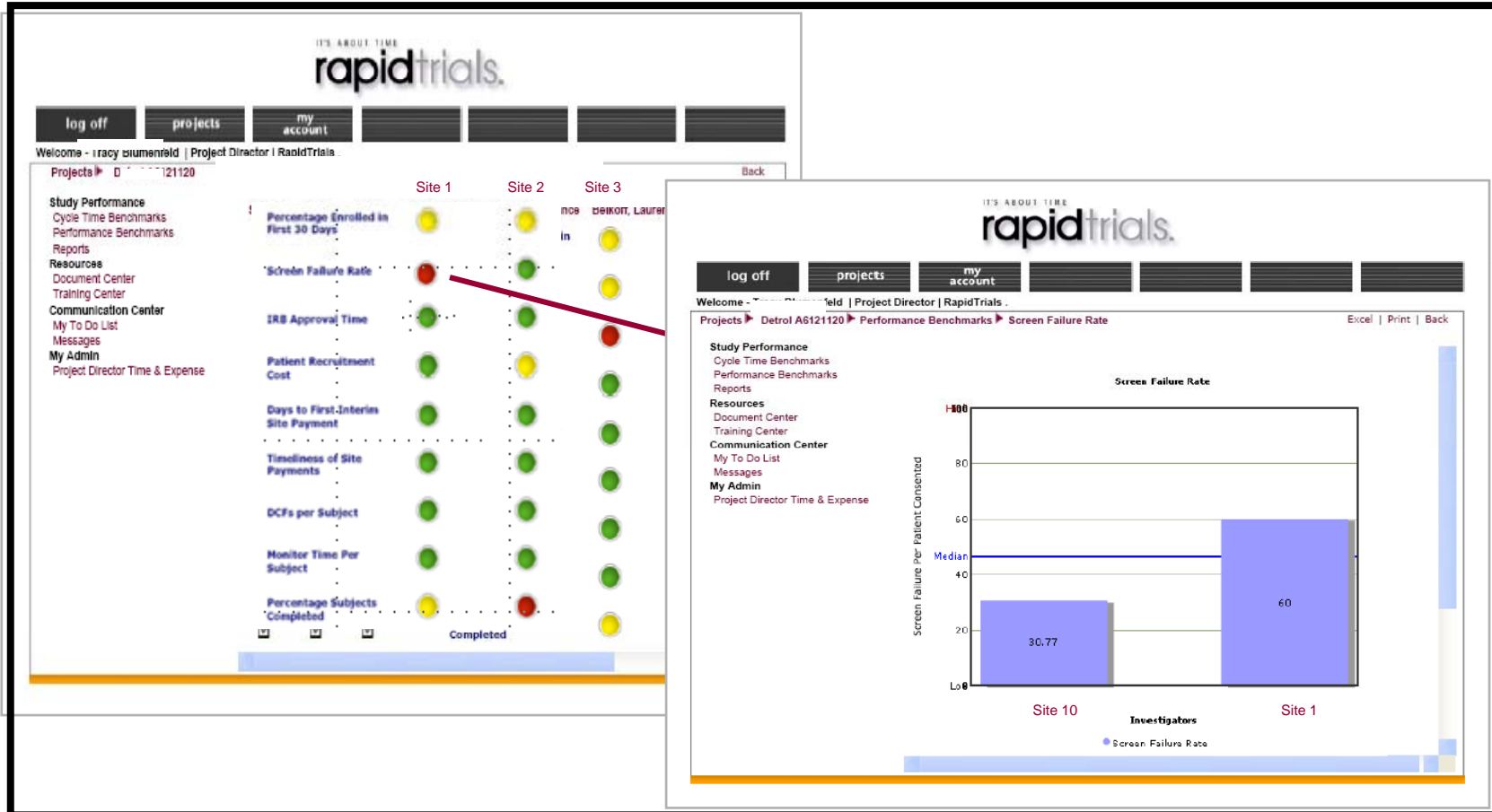


 CRC availability

# Forecast, Plan, Then Pressure-Test



# Measure and Benchmark ...



# ... and Course-Correct

IT'S ABOUT TIME  
rapidtrials.

log off projects my account

Welcome - Tracy Blumenfeld | Project Director | RapidTrials .

Projects > Reports > Screen Failures by Type Excel | Print | Back

**Study Performance**  
Cycle Time Benchmarks  
Performance Benchmarks  
Reports

**Resources**  
Document Center  
Training Center  
Communication Center  
My To Do List  
Messages

**My Admin**  
Project Director Time & Expense

Sponsor Name: P  
Protocol Name: D  
Protocol Number: A  
Study Drug Name: T  
Phase: II  
Current Date: 0  
Date Valid Thru: N  
Investigators: I

Type	Enrollment Criteria (Click on criteria below to drill down)	Number of Screen Failures
1. Inclusion Criteria	In 4. Mean number of OAB micturition episodes ≥ 3 per 24 hours as verified by the Screening micturition diary prior to randomization/Visit 2 (OAB micturition is defined as micturition episodes a ...	5
2. Inclusion Criteria	In 5. original International Prostate Symptom Score (IPSS, 0-35) > 12, with IPSS QoL (0-6 point) > 3 at Visit 2	1
3. Inclusion Criteria	In 6. Rate their bladder condition at Screening as "Some Moderate Problems", "Severe Problems", or "Major Severe Problems" on the Patient Perception of Bladder Condition questionnaire	1
4. Inclusion Criteria	In 7. Ability and willingness to correctly complete the micturition diary and all the trial related questionnaires, comply with scheduled visits and comply with trial procedures	4
5. Exclusion Criteria	Ex 20. Significant hepatic or renal disease, defined as twice the upper limit of the reference ranges regarding serum concentrations of AST, ALT, ALP, urea nitrogen, or creatinine	1

Single entry criteria accounting for most screen failures

## Intervention

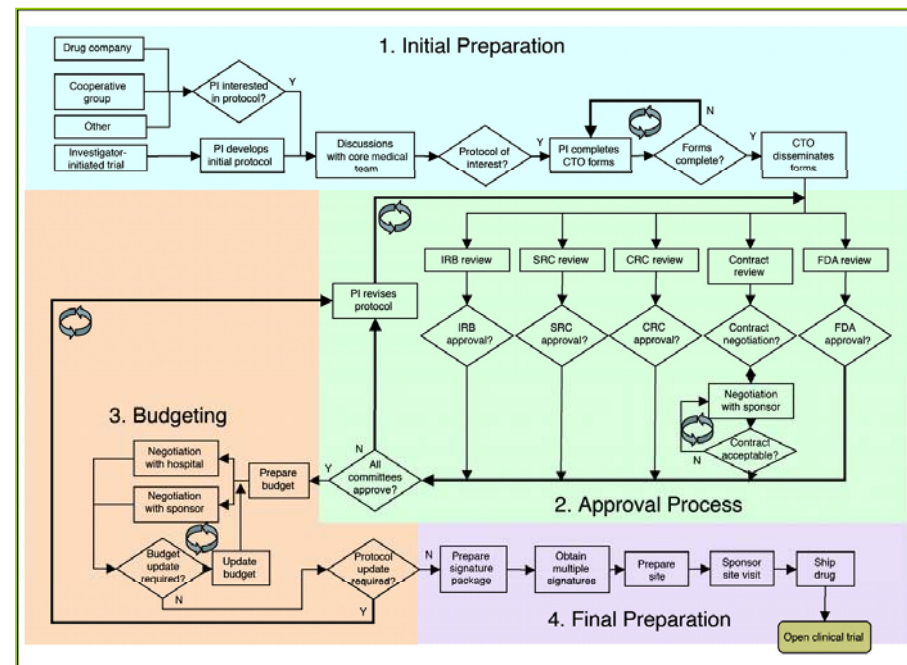
- Reviewed screening of incoming calls prompted by advertising
- Wrote more in-depth phone-screening script
- Obtained IRB approval for new script
- Implemented new script to reduce screening visits

## Impact

- Reduced screen-failure rate by 35%
- Enhanced role of lower-cost staff
- Freed PI and study coordinator for other activities

# In Summary

- **Academic centers have focused on ...**
  - **Scientific merit of the investigational drug**
  - **Protection of patients**
  - **Protection of IP (contracts and grants administration)**
- **And now can also focus on ...**
  - **Forecasting, planning and implementation**
  - **Management: people, systems and processes required to succeed**



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# Q&A

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