

After all these years, **Why**  
don't we know more about  
best practices in clinical  
trial recruitment??

Rose Mary Padberg, RN, MA  
National Cancer Institute  
SWOG Spring meeting

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### Outline of today's presentation

- Clinical trial recruitment—what do we know
- Common barriers and what is being done to address them

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Clinical research is the lifeblood of our health  
care system,  
yet ...  
effective, efficient, and inclusive enrollment  
has long been recognized as a challenge.

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## Brief summary of the challenge

- Urgency: 1.4 million **new cases** of cancer in 2008; 565,650 **deaths**...more than 1,500/day
- Need: New and effective cancer treatments
- Solution: Rapid completion of cancer clinical trials
- Problem: **3-5 % eligible patients enroll!**

ACS Facts and Figures 2008

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## What is the research community doing about this important problem?



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## Insanity...

"...is doing the same thing *over* and *over* again, *but* expecting different results."

A. Einstein

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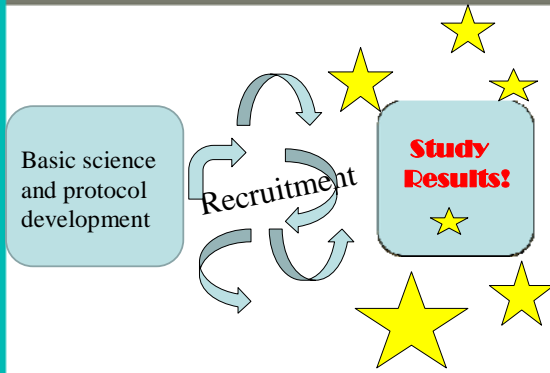
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### Track to recruitment



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### We need to invest in building the bridge



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### Review of Best- Practices for Clinical Trial Recruitment



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## Topical areas of our ongoing research on locating best practices

- Interviews with members of key national Associations involved in clinical trials
- Cancer Clinical Oncology Program (CCOP) investigator and clinical staff interviews
- Site visits to NCI-designated Comprehensive Cancer Centers to observe and interview CT recruitment staff
- Review of the literature

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## Some of the key findings of this search

- Need for public awareness and education
- Important role of the physician
- Protocol design drives enrollment
- Actively reach out to local physicians and lay community
- Adequate funding of clinical research is essential

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## Public awareness and education

- Campaigns can raise awareness about clinical research
  - Building awareness takes time
  - Involve providers
  - Target efforts for specific populations
- Additional research needed
  - Unclear if awareness impacts enrollment
  - How to dispel myths and fears of clinical research
  - How to partner with communities to identify priorities

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## Clinical research has an image problem

Which form of medical participation makes the greatest contribution to mankind?

- #1 Donating an organ
- #2 Giving blood
- #3 Raising money for charity
- #4 Participating in a clinical trial

Survey of 1000 people by CISCRP in 2006

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## Known concerns regarding clinical research



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## Change the Image of "Guinea Pig" to...

Medical hero



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### Donation to NIH Clinical Center to honor participants in clinical trials



"Emergence"  
from NSABP

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### Role of the physician

The physician,  
especially the oncologist,  
is the primary trusted source for  
presenting a Clinical Trial

Siminoff 2008

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### Invitation to enroll

"The greatest source of lost opportunity for recruiting patients is physician failure to mention the option of a trial to an eligible patient .

We have met the enemy...and it is us!"

R. Comis, Coalition of  
Cooperative Groups, 2005

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## Where do people learn about clinical trials?

- Any physician (73%)
- Other health professional (6%)
- Web or online (5%)
- Newspaper, magazine, print (4%)
- Support or advocate group (3%)
- Family / friends (2%)

165 of survivors with cancer :  
Coalition of Ca Coop Grp 2007

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## Continued...

- 94% of Americans say their doctor has never talked about participating in clinical research
- Yet, 75% of those offered a trial, enroll !
- Consistent survey results show that participation was positive, valuable, and rewarding

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## Satisfaction with participation

- Felt they were fully informed (97%)
- Felt they were treated with dignity and respect (96%)
- Had a positive experience (92%)
- Felt like a "guinea pig" (9%)

Coalition of Cancer  
Cooperative Grps 2007

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### Condensed finding from the literature on successful enrollment

*Just ask!*

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### Protocol Design drives enrollment

- Use study designs that do not over-burden the pt
- Design protocol with patient in mind
  - Ease screening requirements and eligibility
  - Questionnaires need to be brief
- Recruitment plan that flexes with changing needs
  - Adequate resources
  - Mix of strategies
  - Realistic recruitment goals based on pt population
  - Track accrual!

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### Provider Outreach

- Develop a systematic approach to informing community physicians about active trials
- Maintain good relationships by providing consistent follow-up on referred pts
- Collaborate with professional societies and advocates

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## Community / consumer outreach

- Flexible recruitment plans—revisit frequently
  - Adequate resources for outreach
  - Have a variety of tactics, drop those that don't work
  - Tailor materials to be culturally competent
  - document data-driven decisions—"why you did what you did"
  - incorporate lessons learned
  - Web sites are helpful for certain audience

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## Fund research to identify best-practices



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## Types of questions that we are asking at clinical sites

- Once a new trial opens, what happens next? What processes are followed to plan recruitment?
- What are the roles of the staff?
- How is recruitment tracked over time?
- Once a trial is open, how do referring physicians learn about it?
- Are there training opportunities to enhance staff expertise?

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## Promising themes bubble up from these interviews

- Leadership and Clear mission from the top
- Standardized pre-screen mechanism
- Collect and analyze data
- Staff training and education
- Community outreach

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## Other clinical trial recruitment activities

- The Trans-NCI CT work group
  - Workshop
- The web-based tool of recruitment strategies
- Other ideas
  - Education of health care providers

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## New! Including CT in your practice

- Web-based course for novice cl. research staff
- Benefits and responsibilities of conducting NCI-trials
- Preparing your site for trials
- Establishing a research team
- Recruiting and enrolling participants
- Ensuring data integrity

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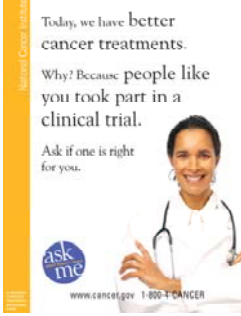
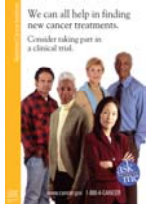
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# New! NCI Promotional materials to assist you in recruitment



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