

Enhancing the culture of patient contributions to learning in health care

IOM Workshop April 1, 2010

Diane Simmons, President and CEO

Center for Information and Study on Clinical Research Participation



Presentation Overview

- n **Current Culture**
- n **Key Learnings from Public Surveys and Focus Groups**
- n **Outreach Initiatives and Their Impact**
- n **Opportunities with Education and Outreach**
- n **Conclusions**

Public Confidence & Trust Today

General Public Attitudes:

70%-83% of Americans believe clinical research is ‘very important’ or ‘essential’ to advancing public health

Perception of Clinical Research Professionals:

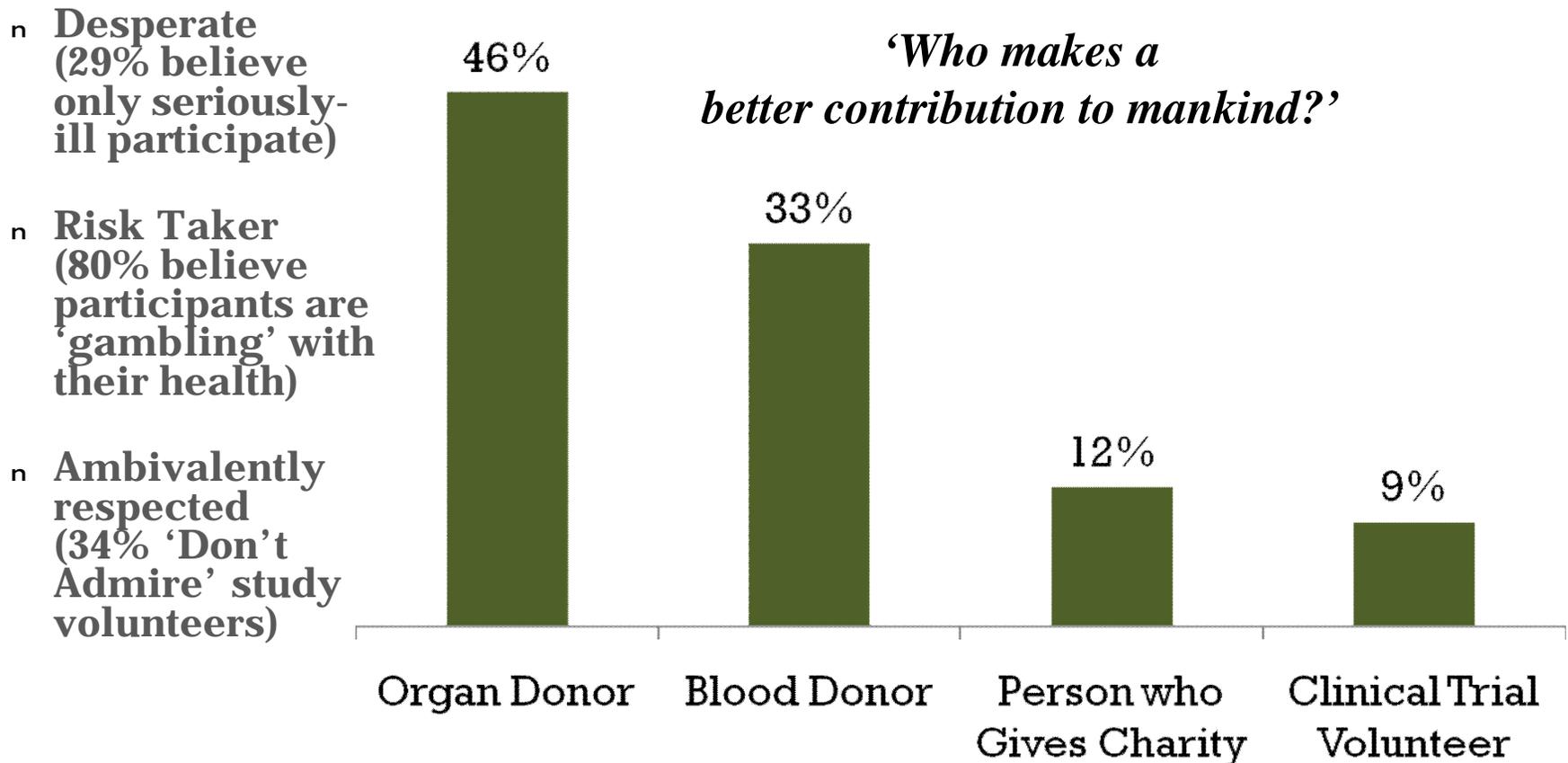
42% of Americans distrust biopharmaceutical companies; only 14% believe they are ‘honest’ to public (similar rating for tobacco, oil & used car sales industry)

31% of Americans believe the FDA is effective at ensuring public/patient safety

25% of Americans believe that PIs and study staff are solely motivated by greed

Sources: Research!America (JAMA, 2005); Kaiser Foundation (2008); Ohmann (2004); HarrisInteractive (2002, 2004, 2007)

By Extension... perception of the Clinical Research Participant



Source: CISCRP, 2006; N=900

Assessing Impact

- § Despite \$600mm spent annually on patient recruitment advertising, 90% of all trials fail to enroll the required number of patients within the contract period – up from 79% in 1997
- § Only 59% of randomized patients enroll and less than half of those enrolled complete a trial
- § One-third of all clinical trials must resort to Rescue Mode recruitment
- § Less than 17% of volunteers report that they learned about clinical trials from their primary/specialty care physician
 - § Greater disparities among minority patients
- § Less than half of physicians refer patients into clinical trials with a typical referral rate of <1% of community served

(TCSDD, 2007)

Focus Groups:

Probing for factors that most inform and educate clinical research participants

Summary Findings:

- ∅ There are **4 core motivations** of all study volunteers regardless of age and socio-economic status.
- ∅ Study **staff play an essential role** in volunteer retention and compliance.
- ∅ Compensation and **incentives cheapen and trivialize the value** of participation.
- ∅ The **LPLV mindset alienates study volunteers** and creates a sense of discontinuity.

Conducted 3/2009 at PMG in North Carolina; convenience sample of 22 study volunteers; 3 groups: under age 30, aged 31-50 and over age 50; even split male/female; range of socioeconomic backgrounds and medical histories



Focus Groups:

Probing for factors that most inform and educate clinical research participants

4 core motivations of all study volunteers regardless of age and socio-economic status:

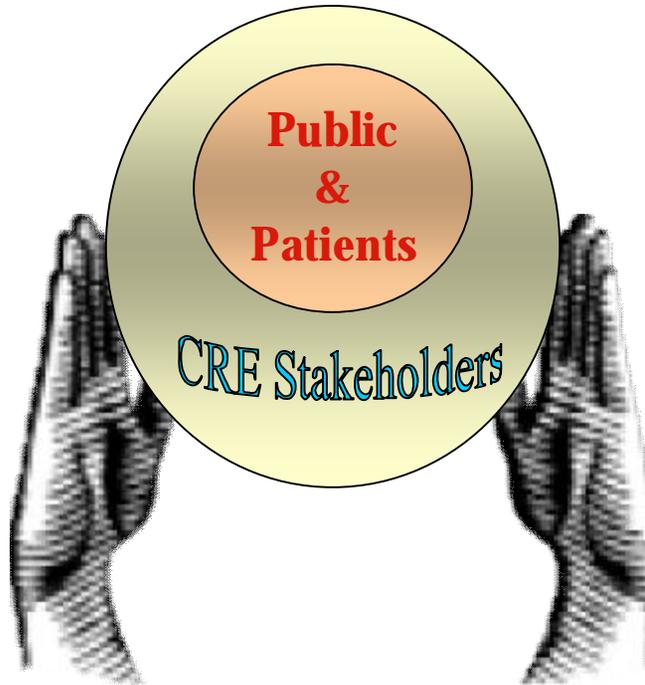
1. **Want to feel they are taking control of their medical condition and well-being**
(structured environment provided by site staff and protocol; feeling obligated to themselves, their families and the study staff)
2. **Want to develop personal relationships with study staff**
(feel accountable to research coordinator; medical and emotional support sustained pre-, during and post-trial)
3. **Want to be treated as human beings**
(patients appreciate the interactions; object to being called “subjects”, want to be acknowledged for investing their time and their bodies)
4. **Want to know their participation will make a difference**
(eager to learn the outcome; have access to trial results and whether they were in the control or test group)

CISCRP's Public Outreach Initiatives



National Outreach and Education

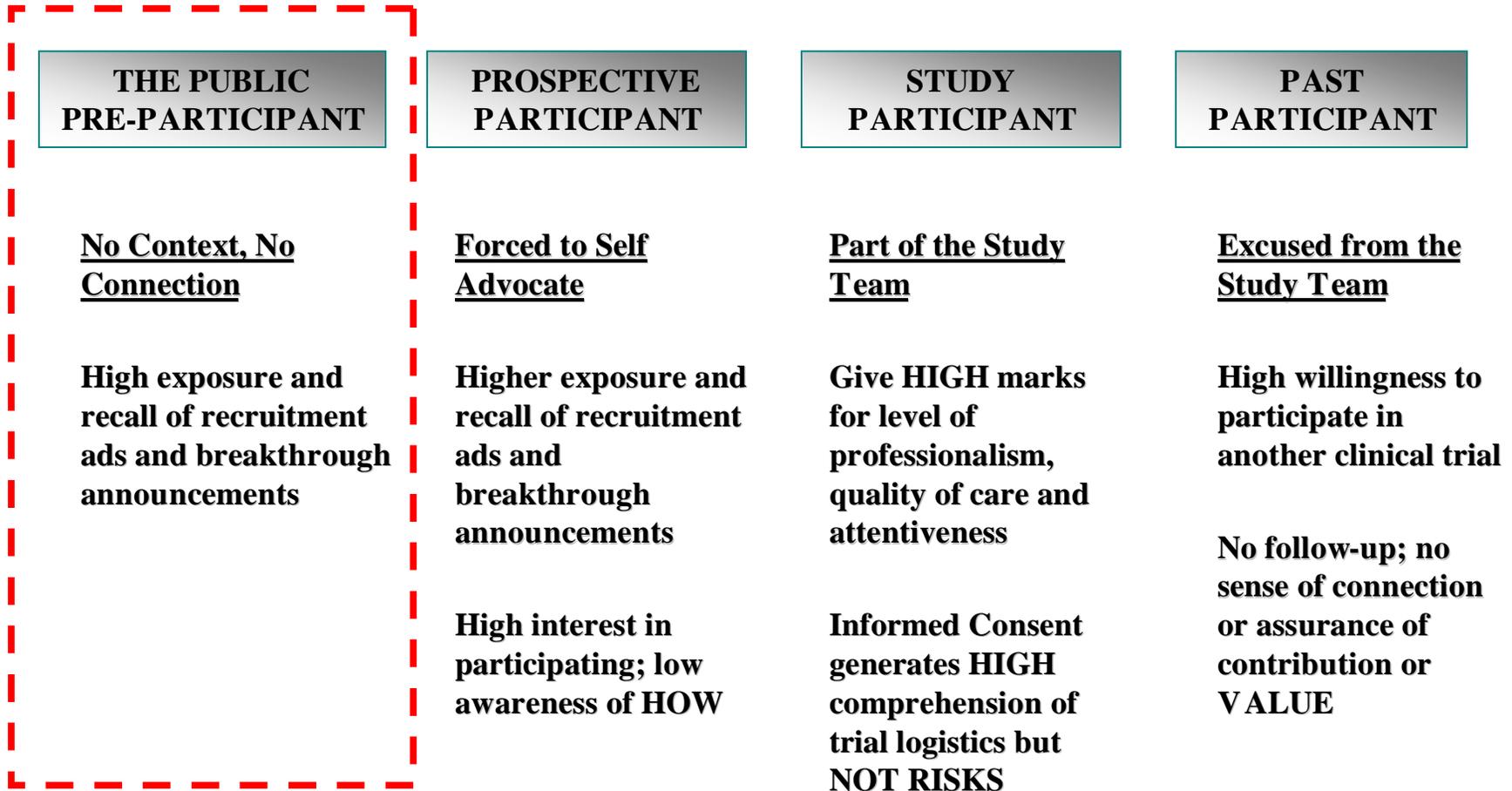
- PSAs – Medical Heroes
- CISCRP Membership
- Edutainment
- Media Outreach
- Original Research
- House Resolution 248
- ‘Appreciation’ legislation
- Post-Trial Results
- Search Clinical Trials



Local Outreach and Education

- AWARE for ALL
- Educational Materials (pre- and post-trial)
- Medical Heroes packets
- Speakers Bureau
- Media Outreach
- Science Museums
- HS Science Initiatives

Four Distinct Patient Communities



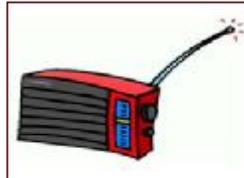
'Medical Heroes'

Public education media campaign

- Not study specific; addresses broader benefits of clinical research
- Collectively embraced by all stakeholders in clinical research and healthcare
- Longevity



Medical Heroes **Print** – series of 5 print ads (different ages, races, genders and occupations)



Medical Heroes **Radio** - radio spots (two 30-second and two 60-second) complement the print ads



Medical Heroes **TV**
preview on www.YouTube.com

Complementing trial-specific recruitment messages

Public education and outreach *impacts not only long term awareness and support but also short term recruitment and enrollment rates.*

Where patient advocacy groups, investigative sites and corporations are already buying print, radio or TV media, they are exchanging 5% to 10% of their recruitment ads with 'Medical Heroes.'

- § Market test by Eli Lilly: Ran the 'Medical Heroes' campaign concurrent with recruitment ads for a pain study in 30 sites across 18 different US locations. Market test result: 38% increase in recruitment rates.

Using the 'Medical Heroes' print ads as posters and fliers in the waiting rooms of doctors offices, hospitals, and community health clinics.

Playing 'Medical Heroes' radio and TV ads on DVD players in waiting rooms and offices.

Providing visible links online to 'Medical Heroes' campaign.

AWAREforAll



Clinical Research Education Day

3 to 6 months of grassroots outreach in each community



Communicating Post-Trial Results

Patients skeptical that sponsor will share information: Only 14% of study volunteers believe that sponsors will disseminate information-positive or negative-about an investigational treatment (Harris Interactive 2007)

Pilot program sponsored by Pfizer:

Multiple formats

Study staff integral to entire process

Extremely positive reception from volunteers and sites

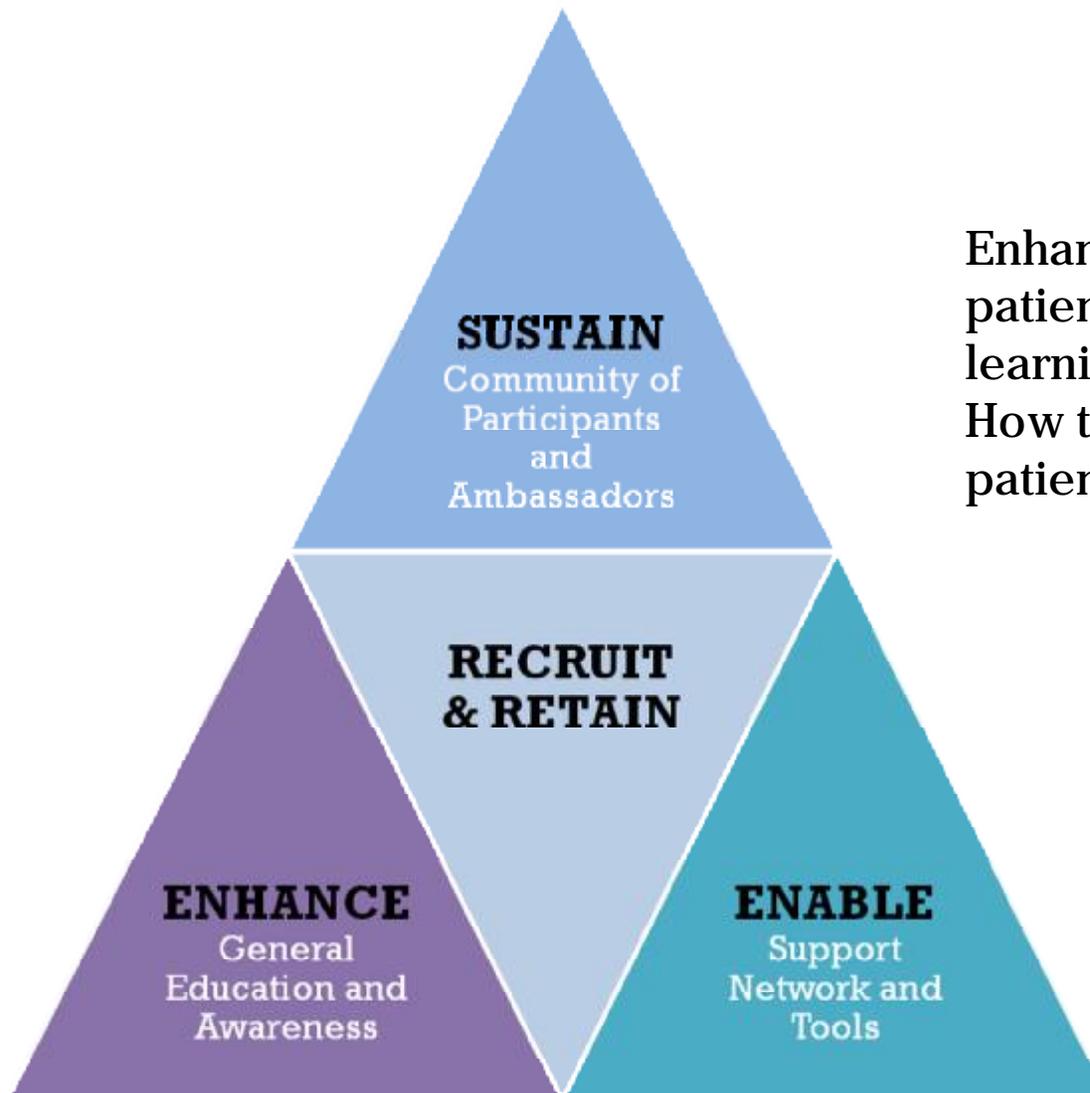
How well do you feel you understand the results of your clinical trial?	Pre - Pilot	Post - Pilot
Very Well/ Somewhat Well	16%	92%
Not Very Well/ Not at All Well	84%	8%

Local Outreach and Education through Science Museums

New Exhibit proposed that will feature:

- § Inquiry-based, multimedia learning experiences focused on the how-to and importance of health research as presented by practicing scientists.
- § An innovative mix of video storytelling and digital support technologies.
- § Showing people how real world scientists conduct their research and create a continuum from basic to translational science to clinical trials that produce new treatments and solutions.
- § Highlighting what it means to participate in a clinical trial, and the impact that participation has on science and drug discovery.
- § Designed as a travelling exhibit available to all US-based Science Museums.

Conclusion: Portfolio of Strategic Initiatives



Enhancing the culture of patient contribution to learning in health care: How to get input from patients?