

# OBSTACLES TO ENROLLMENT



# OBJECTIVES

1. Identify attitudes and barriers to enrollment and recruitment
2. Describe key components of an effective recruitment and enrollment plan
3. Discuss common motivational factors for participation in a trial
4. Discuss strategies to improve the enrollment and recruitment

# Scenario 1

- A cardiologist is involved in a randomized placebo controlled clinical trial testing a novel agent for use in patients with heart failure. The trial is well designed and the outcomes to be studied are reduction in morbidity and mortality after 5 years of follow up. During a routine office visit, a 45 year old female patient reports worsening of symptoms related to her heart failure, despite being on appropriate medications. She meets the inclusion criteria listed in the study. However, despite telling her about the trial and its benefits, she refuses to participate in the trial.

## Scenario 2

- An investigator in a hospital in New York area conducted a prostate cancer prevention trial. The study design was a randomized controlled trial comparing PCPT123 drug to placebo in men older than 55 years of age. An “a priori” recruitment goal of having at least 10% of the study population to be African American men older than 55 years of age was set. This was based on the national proportion of African American men older than 55 years but only 2% of the study population ends up being older and agreed to participate in the trial. The trial was completed with only 1 % of African American men older than 55 years.

# **1: Identify Attitudes and Barriers to enrollment and recruitment**

- Patients attitudes and barriers
- Physicians attitudes and barriers
- Lack of information
- Barriers specific to specific population
- Role of research staff

## **2. Describe key components of an effective recruitment and enrollment**

- Awareness
- Knowledge of the protocol
- Study design
- Sample size, inclusion and exclusion criteria
- Planning and timeline
- Resources
- Trained staff
- Site
- Recruiters role

### **3. Discuss common motivational factors for participation in a trial**

- Physicians advice
- Therapeutic benefit
- Altruism
- No other treatment option
- Free medication and diagnostic testing
- Curiosity

## **4. Discuss strategies to improve the enrollment and recruitment**

- Education
- Mechanisms of recruitment
  
- Advocacy groups in the community
- Advertisement
- Involvement of the families, social workers
- Use of technology

## **Patient attitudes towards trials**

- Clinical trials are important/not important for advancement of treatment
- If worth the time
- Low income population disagrees with the importance of trials than indicating that they don't know the value
- Problem not with the attitude but unavailability of appropriate trial and eligibility

## Awareness

- Lack of awareness
- Understanding the idea behind clinical trial
- Patients or family members don't ask about trials
- Gender differences in hearing about trials
- Older more aware of trials
- Those on east and west coast more likely to hear about trials than south

## **Participants barriers**

- Fear of experimentation
- Fear of unknown
- Protocol concerns
- Concern about cost
- Lack of insurance
- Difference between SOC and research
- Logistic concerns
- Concern re treatment
- Risk vs benefits
- Research than treatment
- Misconception that trials are invasive
- Time off work
- Language

## **Physician as a Barrier**

- Unaware of trial process
- Protocol design is complex
- Role of physician researcher
- Time crunch
- Limited resources and knowledge
- Misperception that control arm is always a placebo
- Lack of diversity on research team
- Ineffective guidance to study staff
- Ineffective ICF process

## **Barriers specific to Elderly**

- Co-morbidities
- Logistic issues -transportation
- Non compliance
- Lack of trust
- Rely on community or family member

## **Barriers specific to the minorities and economically disadvantaged**

- Lower rates of accrual
- Mistrust of the researcher
- Access to health care
- Tuskegee trial knowledge
- Lack of minority physicians and staff to recruit cultural beliefs
- Native Americans perceptions
- Asians -decision making by the family
- Stereotyping by researchers that non compliant
- Language barriers
- Illiteracy
- Geographic locations

## Recruitment of Study Subjects

- Most common reason for a clinical trial failure
- At least 80% of pharmaceutical trials do not meet enrollment deadlines
- Investigators/sponsors should plan recruitment strategies, feasibility of recruitment before initiation

## **Recruiting strategies**

- Clinical trial literacy
- Advocacy groups
- Advertise
- Eligibility
- Contact through different sources
- Improve attitudes and knowledge through campaigns
- Feedback to referral resources

## Recruiting from Clinics

- Informing physicians directly
- Direct mailing to patient from clinic staff is possible if letter comes from clinic physician
- Direct patient approach at clinics has issues with HIPPA
- Sometimes conflict between research and treatment

# Addressing Low Recruitment

- Re evaluate the sample size
- Replace sites that are not enrolling in a time frame
- Add new sites
- Extend the recruitment period
- Modify inclusion criteria and exclusion criteria

## **Strategies for patients likely to drop out**

- Increase communication
- Respond to complaints
- Consider decreasing workload, number of blood draws
- Reduce frequency of study visits

# Retention of Participants

- Keeping subjects in the study
- Important for the validity of results
- Retention is closely linked to satisfaction
- Begins with recruitment materials, consent signing
- Treating participants with respect
- Communication between research staff
- Communication about disease process
- Attention to participants problems

## In summary recruitment:

- Depends on the type of study and population
- For clinical trials, information material, advertising, mailings, internet, databases posters, flyers, social networks, clinic recruitment, referrals, community leaders
- Alternative recruitment strategies for minorities, elderly and specific populations

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- B. Spilker and J.A. Cramer, Patient Recruitment in Clinical Trials (Raven Press, New York, 1992)
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<http://www.youtube.com/watch?v=2egldb3hNBg>

<http://www.youtube.com/watch?v=0hcsho6XxkI>