Developing and Maintaining a Profitable Research Center from the Doctor’s Perspective

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Objectives

1. Discuss the infrastructure necessary to establish a successful and productive research center.
2. Discuss the challenges of maintaining a successful research center while competing in global clinical trials.
3. Identify strategies for promoting your research center and enhancing your chances for clinical trial selection.
Traditional Roles of a Physician Director

• Active participation in clinical trials
  – Oversee patient recruitment and enrollment
  – Medical history and PE
  – Review charts and laboratory results
  – Assess and manage adverse events
• Marketing the site
• Attending Investigator meetings
• Hiring and managing personnel
• Business aspects
  – Negotiating Contracts
  – Review revenues and expenses
Was has changed?

Marketing your site:

– Global competition
– Physician marketing to Pharma is less effective
  • Still necessary for young PIs
– CROs select site based on past performance
– Just do a good job!
  • Hire and retain competent and productive CRCs
  • Achieve enrollment goals
  • Complete studies on time
  • Clean source documents with minimal queries
  • Minimize screen failures and dropouts
  • Track your metrics on each study
Management Styles

• Directive (coercive)
• Authoritative (visionary)
• Coaching (developing new staff)
• Pacesetting (follow me)
• Participative (Democratic)
Clinical research is a team sport!
Key component: Team Leaders

Experienced, successful study coordinator with “hands on” clinical research and leadership experience

- Regular team meetings over lunch; PI should attend and play a supportive role
- Directs recruiting, interviewing and hiring new staff
- Train new staff *Coaching ➔ Pacesetting*
- Active research coordinator (lead by example)
- Participates in the budget process
- Identifies and troubleshoots problems
- Communicates with CROs
- Follows screening/enrollment progress of all trials
- You can have more than one team leader!
Key components: Clinical Coordinator

Hiring new staff – desirable traits:

– Team player
– Work ethic and good employment history
– Medical training: RN, Respiratory therapist, MA
– Compulsive personality type (attentive to detail)
– Multi-tasker
– Personable, friendly, outgoing, likeable, and a good listener
– Telephone/communication skills are essential to be an effective recruiter
Developing a Research Coordinator

Training

- 2-3 year learning curve
- Direct supervision of a “Mentor and Coach”
- First assess potential for success
  - *Does this person want clinical research as a career?*
  - *Can this person do the job?*
  - *Assign tasks or studies that match abilities*
  - *Assign progressive responsibilities*
  - *Identify abilities and limitations of each CRC when assigning tasks!*
- Learn every aspect: source documents, telephone recruitment, venipuncture and lab specimens, clinical site visits
- Ideal Goal: To train a fully independent coordinator that can manage at least 4-5 studies, however ....
Key Role of the MD: Retention of staff

Exercise participative (Democratic) leadership

– Create a warm, friendly work environment
– Encourage employee input in decision making
– Professional enrichment: sponsor travel to meetings
– Motivate by frequently rewarding team effort and good outcomes
  • Quarterly performance-based bonuses
– Be sensitive to personal needs of your staff
  • e.g., child care, flexible scheduling
– This approach is possible with highly motivated, self-directed and competent employees.
Key Components of a Successful Site

1. Clinical research facility with infrastructure – e.g., overnight facility, induced sputum
2. Coordinator – Director
3. Coordinator – regulatory, IRB, collections
4. Effective process for negotiating budgets
5. **Hire and retain** competent, motivated and productive research coordinators
6. Commit adequate financial resources for suitable employees and infrastructure
Thank you