

# CLINICAL TRIALS

## OPPORTUNITIES AND CHALLENGES

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# CLINICAL TRIALS

## What is a Clinical Trial?

- A research study that enrolls human volunteers to test a medical treatment.
- A new or old drug, device, procedure, lifestyle measures
- Strategies for prevention, diagnostic tests and quality of life issues.

# CLINICAL TRIALS

## What are the Phases of Clinical Trials?

- Clinical Trials are undertaken for many reasons
- To gain approval from the US Food and Drug Administration ( FDA)for a new Drug or treatment. To gain full approval for a Drug takes several steps.
- Human trials move through four phases. A new drug must pass each phase before moving on to the next.

# CLINICAL TRIALS

## OPPORTUNITIES

### Why Become an Investigator?

- Intellectual Challenge
- Cutting edge
- Options to patients Additional Revenue stream
- Stature among peers
- Marketing Tool
- Opportunity: advisory Boards, Consultant, Speaker
- Publications

# CLINICAL TRIALS

## OPPORTUNITIES

### What makes a good investigator?

- Leadership and Managerial skills
- Attention to detail
- Integrity
- Independence
- Intellectual curiosity
- Clinical knowledge
- Willingness to engage and follow Good Clinical Practice guidelines.

# CLINICAL TRIALS OPPORTUNITIES

## Locations of Recruiting Studies

Total N = 36,255 studies  
(Data as of July 26, 2015)

Non-U.S. Only (53%)

U.S. Only (41%)

Both U.S. and Non-U.S. (6%)



# CLINICAL TRIALS

## Challenges

- Regulation by government agencies
- Funding to offset delays in sponsor payments (ongoing cash flow)
- Do not fund with your clinical practice
- Start a new business venture. Independent or integrated into your existing practice
- Finding and maintaining a trained and dedicated study team/support staff
- Building relationships
- Time commitment and Responsibility of a PI

# Studies per Physician

- What are your recommendations?

In a small group practice, a physician can balance 2-3 active studies with his/her practice, depending upon the size, number of physicians in research, and the trial's phase and complexity.



# AVERAGE PER PATIENT GROSS REVENUE

SPECIALTY	GROSS REVENUE
GASTROENTEROLOGY	\$6,500
ENDOCRINOLOGY	\$6,900
HEMATOLOGY	\$7,500
REPRODUCTIVE	\$7,200
ANTI-INFECTIVE	\$8,900
CNS	\$9,000
ONCOLOGY	\$9,800

1999-2007

Source: State of the Clinical Trials Industry, Thomson CenterWatch, 2006, Boston, MA

# CLINICAL TRIALS

## ACADEMIA VS PRIVATE PRACTICE

### Is Success Comparable?

ACADEMIA	PRIVATE PRACTICE
Protected Time	Allotted time
Funding	Industry Sponsorship
Resources (Institution Supported)	Resources (Individual)
Publishing	Group Authorship
Revenue (Clinical/Research Split)	Revenue (Practice Based)

# Business Set-up:

What are the First Steps that you feel are most important?

- Office Space , Supplies, Equipment
- System to track studies
- Marketing
- Research Director
- Staffing/Qualifications
- Certifications for Investigators and CRCs
- Business development Developer
- Contract negotiation

# Recommendations for a Successful Start

Can you comment on a few of these important issues?

- Securing new Clinical trials
- Negotiating Contracts and Budgets
- Local versus Central IRBS
- Selecting and securing trial participants
- Regulatory Documents
- Establishing SOPs, Quality assurance procedures, internal audits

# Where to Start

What are your recommendations?

- Study finder services
- Consultants
- Colleagues
- MSLs
- SMOs

# Costs

Can you comment of some of these issues?

- Start up fees
- Procedural costs
- Hidden cost
- Overhead
- Other

# Stumbling Blocks

What are some common causes for failure?

- Physician too busy
- Inadequate or untrained Staff
- Not enough Time committed
- Poor team coordination
- Physician versus CRC Patient interaction

# Summary

Clinical Research Offers dedicated Physicians:

- The opportunity to Serve patients
- Ability to acquire early knowledge
- Contribute to changes in the way we treat our patients and to the Future of Rheumatology