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.
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.
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
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.
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%)

Reference: Thomson CenterWatch State of The Clinical Trials Industry
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.

Source: Thomson Center Watch Analysis, 2005 Chart 8.19; page 297; PAREXEL Source Book
# Average per Patient Gross Revenue

<table>
<thead>
<tr>
<th>Specialty</th>
<th>Gross Revenue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastroenterology</td>
<td>$6,500</td>
</tr>
<tr>
<td>Endocrinology</td>
<td>$6,900</td>
</tr>
<tr>
<td>Hematology</td>
<td>$7,500</td>
</tr>
<tr>
<td>Reproductive</td>
<td>$7,200</td>
</tr>
<tr>
<td>Anti-Infective</td>
<td>$8,900</td>
</tr>
<tr>
<td>CNS</td>
<td>$9,000</td>
</tr>
<tr>
<td>Oncology</td>
<td>$9,800</td>
</tr>
</tbody>
</table>

1999-2007
Source: State of the Clinical Trials Industry, Thomson CenterWatch, 2006, Boston, MA
## CLINICAL TRIALS
### ACADEMIA VS PRIVATE PRACTICE

**Is Success Comparable?**

<table>
<thead>
<tr>
<th>ACADEMIA</th>
<th>PRIVATE PRACTICE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protected Time</td>
<td>Allotted time</td>
</tr>
<tr>
<td>Funding</td>
<td>Industry Sponsorship</td>
</tr>
<tr>
<td>Resources (Institution Supported)</td>
<td>Resources (Individual)</td>
</tr>
<tr>
<td>Publishing</td>
<td>Group Authorship</td>
</tr>
<tr>
<td>Revenue (Clinical/Research Split)</td>
<td>Revenue (Practice Based)</td>
</tr>
</tbody>
</table>
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 on 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