How to Succeed in Industry-Funded Studies

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Why Consider Industry-Sponsored Research

Total Global R&D Spending

$ US Billions


Source: EvaluatePharma
Industry Sponsored Research – Questions to Ask Yourself

Yes?
- Positive Revenue
- New Therapies
- Good Science
- Networking

Maybe / Maybe Not?
- Revenue ≠ Effort
- Publication Limitations
- Questionable reputation for promotion
Reasons to Consider Industry Funded Studies

- They have a role as part of a balanced portfolio
- Unrestricted funds
- Opportunity for networking with national investigators in multicenter trials
- Provide access for our patients
A High Proportion of Non- and Under-Enrolling Sites

- Well Exceed Enrollment Targets: 13%
- Fail to Enroll a Single Patient: 11%
- Meet Enrollment Targets: 39%
- Under Enroll: 37%

(N= 15,965 sites participating in 153 global phase II and III clinical trials)

Source: Tufts CSDO, 2011
Our Objectives Today

• Explore Opportunities For Industry Research
• Identify Organizational Resources To Keep You Focused, Efficient & Successful
• Appreciate Various Mechanisms for Trial Acquisition
• Understand Industry Quality Metrics
Study Start-Up Processes

- Confidentiality Agreement to Office of Research Administration
- Feasibility Assessment
- Pre-Study Visit/Site Qualifications
- Site Selection
- Regulatory Documents Received at Site
  - Parallel Processes
    - IRB Submission
    - Contract Review
    - Budget Preparation/Negotiation
- IRB Approval then Final Step is Execution of CTA
- Site Initiation Visit

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The Johns Hopkins Clinical Research Network

A Collaborative Approach to Clinical Research

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## Site Performance by Setting Type

<table>
<thead>
<tr>
<th></th>
<th>Mean Time in Months from Pre-Visit through Site Initiation</th>
<th>Mean Time in Months from Site Initiation to First Patient Randomized</th>
<th>Percentage Overall Randomizing At Least One Patient</th>
<th>Overall Actual Enrollment Relative to Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>8.0</td>
<td>2.5</td>
<td>89%</td>
<td>87%</td>
</tr>
<tr>
<td>Independent Physicians</td>
<td>5.2</td>
<td>2.4</td>
<td>91%</td>
<td>96%</td>
</tr>
<tr>
<td>University/Hospital/Government Clinics</td>
<td>9.9</td>
<td>3.1</td>
<td>87%</td>
<td>73%</td>
</tr>
</tbody>
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Source: Tufts CSDD, 2012
Why Partner With Community Sites

Growing Proportion of Community-Based Principal Investigators

<table>
<thead>
<tr>
<th>Year</th>
<th>Independent Physician(s)</th>
<th>University/Hospital/Government Clinics</th>
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</thead>
<tbody>
<tr>
<td>2006</td>
<td>36%</td>
<td>64%</td>
</tr>
<tr>
<td>2008</td>
<td>41%</td>
<td>59%</td>
</tr>
<tr>
<td>2010</td>
<td>48%</td>
<td>52%</td>
</tr>
<tr>
<td>2012</td>
<td>53%</td>
<td>47%</td>
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Source: FDA’s Bioresearch Monitoring Information System File (BMIS)
Johns Hopkins Clinical Research Network - JHCRN

A Collaborative Approach To Research

• NIH and research sponsors are emphasizing the need for community engagement for a broader type of research and participant demographic

• JHCRN Established in 2009 under the auspices for the NIH-funded Institute of Clinical and Translational Research
Affiliated Sites of the JHCRN
Advantages of the JHCRN

• One Network - Access to a large & diverse pool of patients.
• One Prime Contract - Johns Hopkins ORA.
• One IRB – JHM IRB of record.
• One Budget - Maintain consistency
• One point of contact – JHCRN Network Coordinator
• One Johns Hopkins Principal Investigator
• One Lead Site Investigator - each participating affiliate site
Benefits of Working with the JHCRN

• Academic/Community Hospital Regional Collaboration
  – Increase Sample Size
  – Expanded Demographics
• Protocol Design & Feasibility Expertise
• Investigator Database
• Regulatory/Contracting/Budgeting Expertise
• Long-standing Research Experience Across Network
• Dedicated Site Network Coordinators
JH Clinical Research Network

- A regional translational research organization linking Hopkins to a diverse network of community based health care delivery systems.
- Research sponsors come from the private and public sector
- Study designs include clinical trials, PCORI, and comparative effectiveness
- Administrative infrastructure created to expedite research through the sites.
Contact information for the JH Clinical Research Network

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• Web site:
  ictr.johnshopkins.edu/service/jhcrn