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How to Succeed in Industry-Funded Studies

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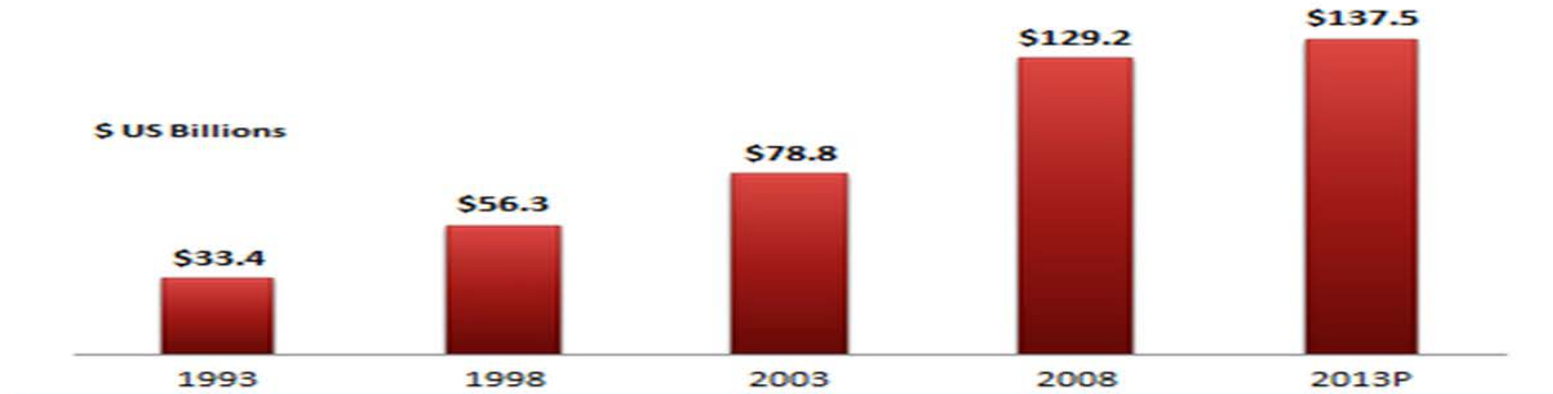
Professor of Medicine

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Why Consider Industry-Sponsored Research

Total Global R&D Spending



Source: EvaluatePharma

Industry Sponsored Research – Questions to Ask Yourself

Yes?

- Positive Revenue
- New Therapies
- Good Science
- Networking

Maybe / Maybe Not?

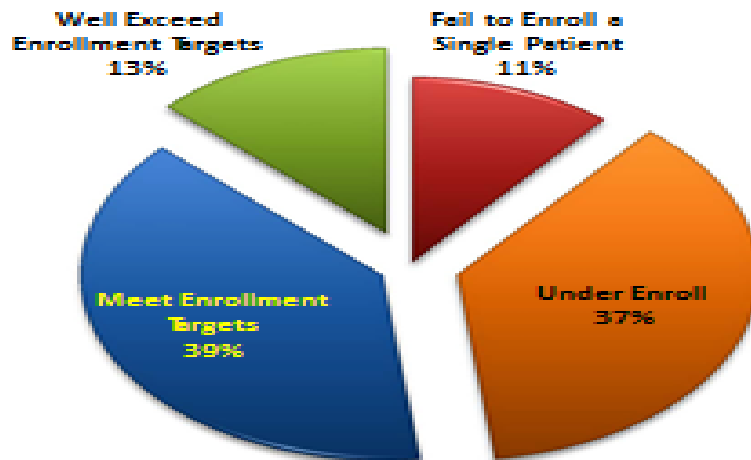
- Revenue \neq Effort
- Publication Limitations
- Questionable reputation for promotion

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

Becoming A Good Statistic

A High Proportion of Non- and Under-Enrolling Sites



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

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

Adrian Dobs, MD, MHS
Director, JHCRN
Professor of Medicine and Oncology

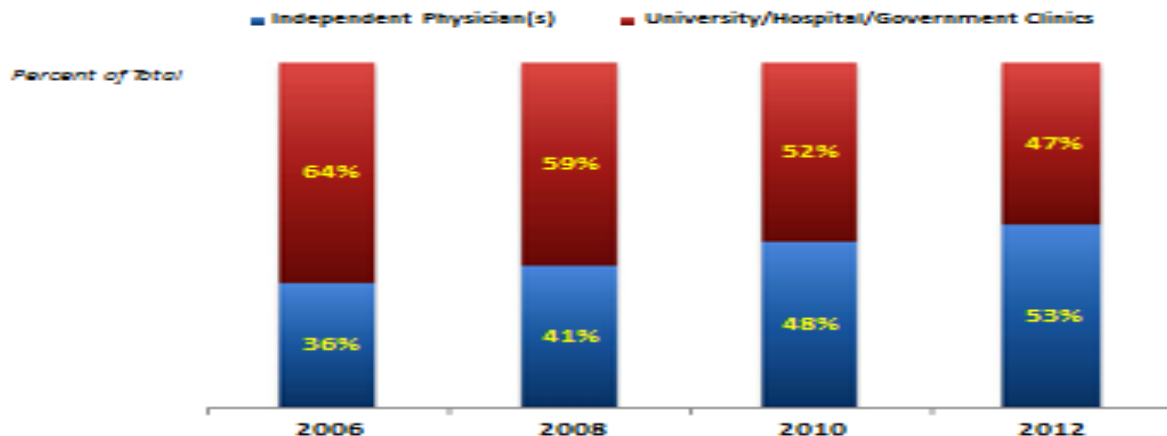
John Niederhuber, MD
Co-Director, JHCRN
CEO, INOVA Translational Medicine Institute

Site Performance by Setting Type

	Mean Time in Months from Pre-Visit through Site Initiation	Mean Time in Months from Site Initiation to First Patient Randomized	Percentage Overall Randomizing At Least One Patient	Overall Actual Enrollment Relative to Plan
Overall	8.0	2.5	89%	87%
Independent Physicians	5.2	2.4	91%	96%
University/Hospital/ Government Clinics	9.9	3.1	87%	73%

Why Partner With Community Sites

Growing Proportion of Community-Based Principal Investigators



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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