

The Clinical Research Unit:

Achieving Success through Industry Sponsored Clinical Trials

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Objectives

- Delineate major differences between industry-funded and other-funded trials
- Acquire information necessary to be a successful investigator and to reliably conduct industry sponsored trials including responsibilities to the Sponsor, the FDA, the Institution and the Patients

Overview

- **Contrasts in Clinical Trials based on funding source**
- **How to Get Started**
- **Assessing the Protocol**
- **Assessing Funding**
- **Factors in Success**
- **Frustrations**
- **Benefits**

Investigator Role in Clinical Trials

	Investigator-Initiated Funded	Investigator-Initiated Non-funded	Industry-Funded
Ideas	You	You	Sponsor and FDA
Conduct	You	You	PI with Monitors
Protocol	You	You	Sponsor and FDA
Statistical Design	You + Institutional Resources	You + Free Institutional Resources	Sponsor Provided
Needs	Study Coordinator + Cooperation	You + Cooperation	Study Coordinator with FDA & Reg. Know-how

Investigator Role (cont)

	Investigator -Initiated Funded	Investigator -Initiated Non-funded	Industry- Funded
Product	Improved Health Care Delivery/ Outcome	Improved Health Care Delivery/ “A Better Way”	Database for FDA Approval
Funding	Grant Award “You get what is given”	“Blood, Sweat and Tears”	Productivity Based “You get what you give”
Publication	PI and Others	PI and Others	Leads from Industry, Lead Enrollers, Lead Names

How to Get Started

- Demonstrate ability
 - Other research, Sub-I role, Academic credentials
- Document resources –
 - Patient volume, Accrual rates, Dedicated Research Pharmacist & Pharmacy
 - Study Coordinators – Helpful experience: CCRCs, RNs, EMTs, Med students, FMGs
 - Sub Investigators – Departmental colleagues, Interdepartmental colleagues to broaden the base of expertise

Find Out What's in the Works

- Industry Contacts
- CROs
- CenterWatch or other Research Journals
- Internet
- Referrals

Funding Considerations

- Set amount negotiated
 - Usually the same across the board
- Are IRB and Pharmacy charges covered?
- What's the Institutional toll?
- Are time and effort compatible with the funding?
- Is there any money left over?

Success

- Compulsion – Fastidious attention to detail
- Cooperation – Enlist good will of staff, residents and nurses
- Presence – BE THERE!
- Planning – Get Ready, Get Set, GO!
- Availability – Beepers, Cell Phones, ANSWER the CALL!
- Accountability – Adherence to Protocol, Approval for Deviations, Control Medications, Consent process, Documentation of EVERYTHING
- Source documentation – record retrieval

Frustrations

- House staff vs. Study – broken protocols
- Irrational demands by monitors, sponsors, CROs
- Patient Non-compliance – Lost to Follow-up, Incarceration, Party time
- Is It Worth the Effort?

Benefits – What's in it for me?

- Money to the Institution - an added value towards promotion and tenure
- Recognition by colleagues
- Money left over for pursuit of other unfunded research interests
- Financial autonomy
- Publications
- Presentations
- Buy out of clinical time