
A strategic collaboration between the International Anesthesia Research Society and the Duke Clinical Research Institute

# *Clinical Research: Making Multicenter Trials Work*

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# Getting Started

- Understanding your goals - different by career stage, practice type, leadership
- Understand resources – infrastructure
- Mentors?
- What is valued?
- Investment vs. participation without risk

# Goals of a Clinical Research Program

- Patients - **contribute to advancing care, offer latest treatments, enhance pt education**
- People - **career advancement, enjoyment, education, enhanced interest**
- Pesos – **dollars to further support education, research infrastructure, mission issues, NIH**

# Conflict

- Patient versus pesos.
- Divulge all other interests with research entity – stock, consulting, honoraria, incentives.
- The need of the not for profit to have an academic or non-money oriented goal – publication, data access, etc.

# The Plan

1. Overall department/ institution vision of centers of excellence (critical mass / synergism vs. lone wolf): Is Clinical Research respected or desired!!!!
2. Individual career objectives (niche)
3. Specific goals and a timeline
4. Assignment of resources

   ***Time***

   ***Space***

   ***Money (grants)***

   ***Mentor***

# Investing in Yourself: Priming the Pump

- Fellowships – Research or Subspecialty combined
- Masters in Clinical Trials
- GCP Courses
- SMO's for early support
- Institutional training courses

# Clinical Databases

- Rich source of data to define significance of question
- Define event rate and associated predictors
- Provide preliminary data supportive of grant opportunities

# DCRI Clinical Database

| | |
|---|---|
| 1960s: | Founding of the Duke Databank |
| 1970s: | Decade of observational research |
| 1980s: | Coordination of multicenter clinical trials and outcomes research/ Integration with Perioperative Database |
| 1990s: | Extensive involvement in multicenter trials; |
| 2000: | Involvement in national patient safety initiatives (CERTS) and Foundation Relations |
| October 2001: | Collaboration with the International Anesthesia Research Society to create GPRO |
| 2005: | Over 350,000 patients and growing |

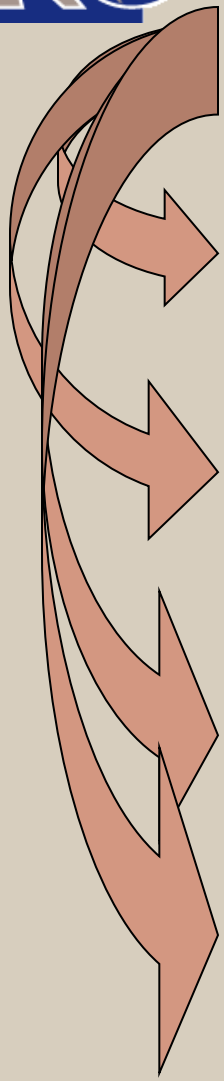
# Funding Opportunities

- **NIH – investigator initiated or RFA response**
- **Multicenter – NIH**
- **Data source**
  - Prospective randomized or observational trial
  - Institutional databases (DDCD)
  - National databases
  - Trial databases

# Funding Opportunities

- **Institution or Department**
  - Seed money – project or career
  - Self investment – fellow, faculty-fellow – primes the pump
- **Investigator initiated – industry trial**
- **Industry initiated – single or MC trial**
- **Investigator initiated competitive grant**

# Industry Initiated Trials



- **Experience**
- **Infrastructure**
- **Margin**
- **Data**

Career Development?

Size

Tenacity

Mentorship

Substudies

Money for other projects

# NIH Trial Design

Pilot trial at one or more sites (? Funding)

Results - Need for large scale trial?

Yes

PI Scientific Grant including site costs

Consortium sites

Coordinating center grant with monitoring, data, statistics, extensive experience trials up to 40,000 patients

No

Single site

# Stages of Trial Development

- Development of key clinical question
- Assessment of relevant question from available relevant data
- Advisory Board (Thought leadership)

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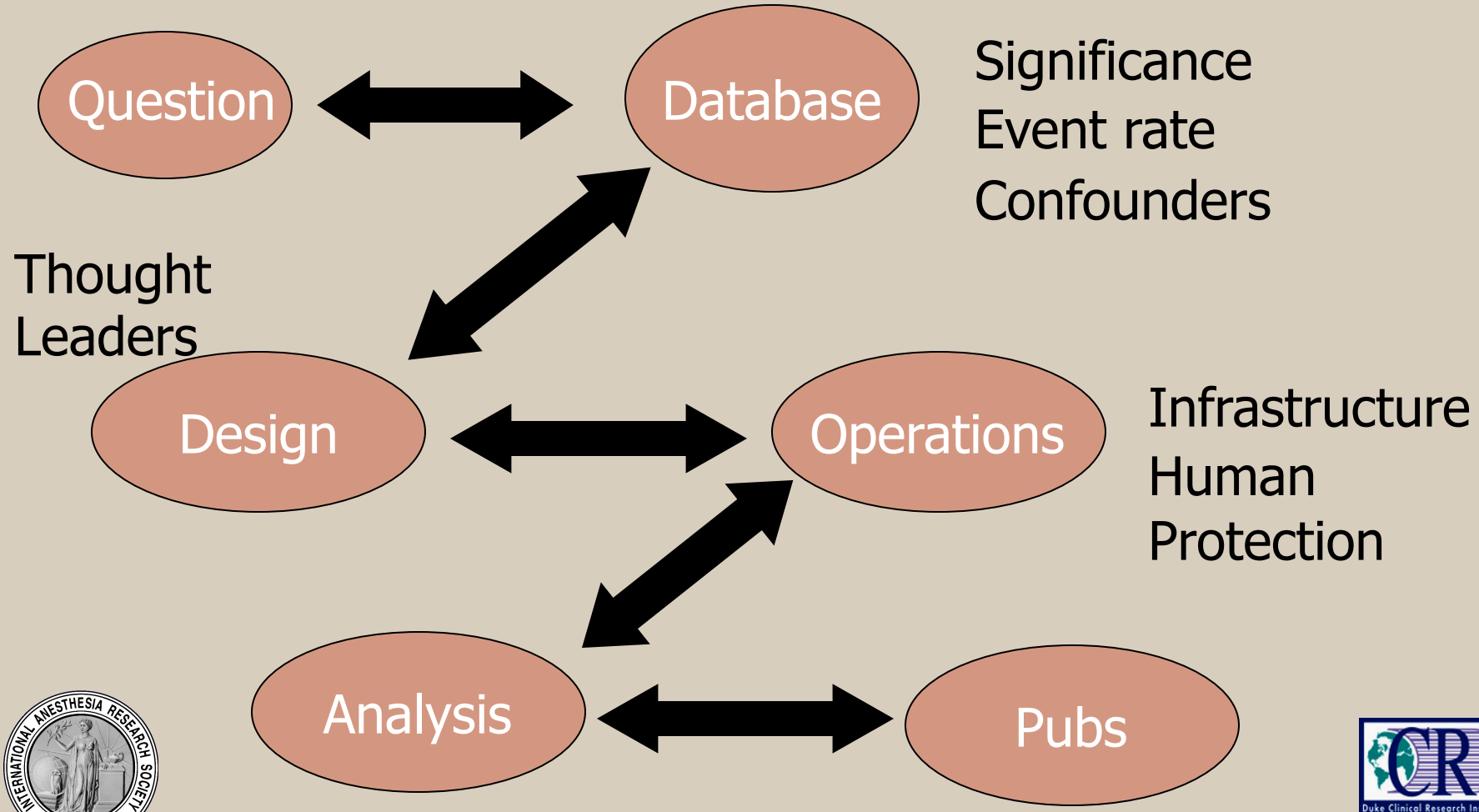
- Pilot or Interventional Trial Design
- Develop operational structure for implementation and enrollment
- Independent data analysis and publication

# Design Process



# GPRO: An Academic Research Organization

**What is an ARO?**

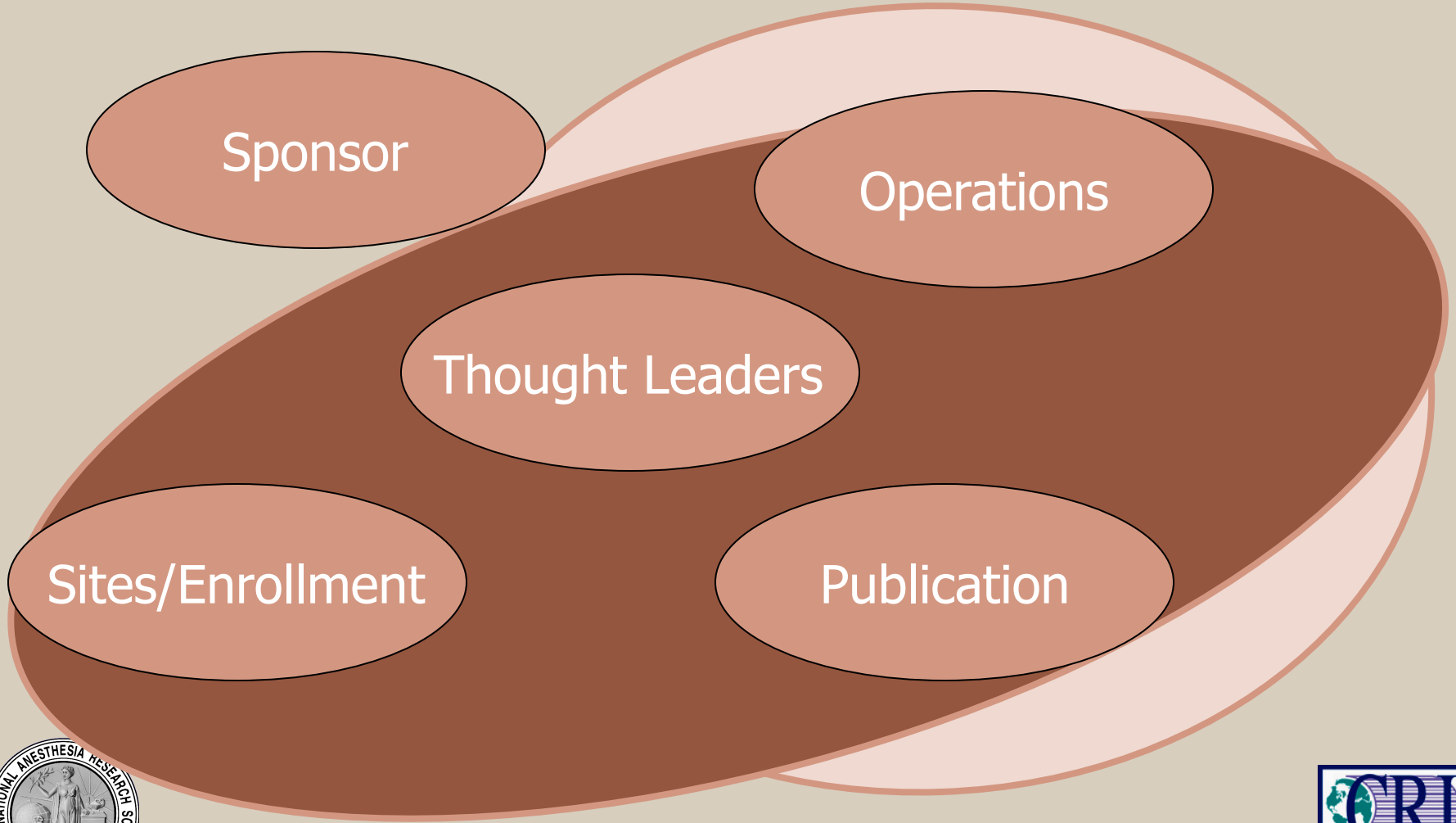
- An academic organization dedicated to:

  *improving patient care by conducting and disseminating good clinical research*

  *providing independent interpretation of the results that increases credibility of trial results*

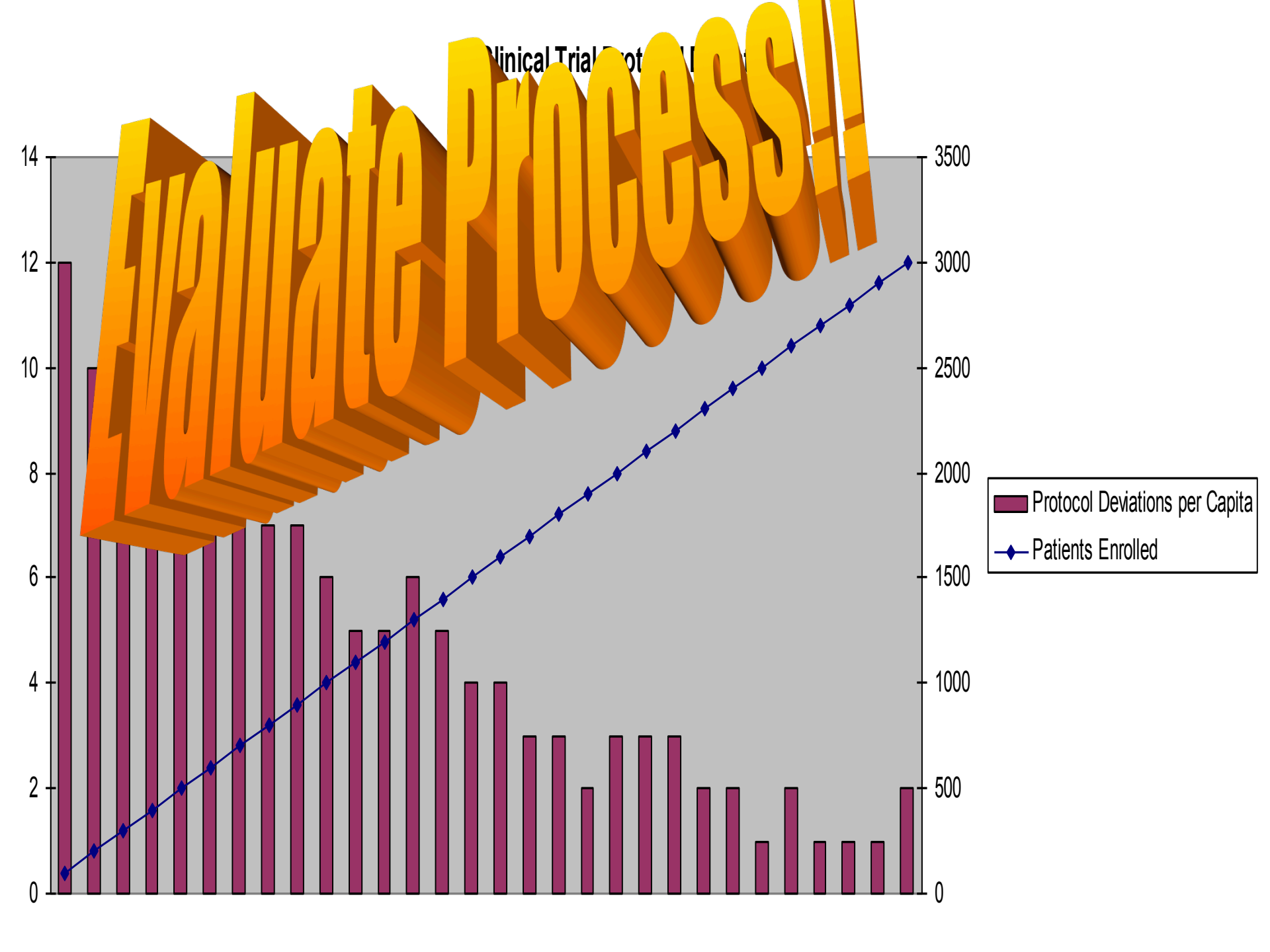
  *improving clinical research methodologies*

# Pieces of the Puzzle



# Developing Networks

- Develop network of key thought leaders and sites
- Understand key clinical questions, issues or controversies in the therapeutic area
- Develop strategies for approaching these questions
- Begin developing credibility with colleagues, funding agencies, industry
- Drive design of trials rather than respond


Evaluate Process!!!
14
12
10
8
6
4
2
0
3500
3000
2500
2000
1500
1000
500
0
Protocol Deviations per Capita
Patients Enrolled

# Preliminary Report on the Use of High-Fidelity Simulation in the Training of Study Coordinators Conducting a Clinical Research Protocol

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Training of health care research personnel is a critical component of quality assurance in clinical trials. Interactivity (such as simulation) is desirable compared with traditional methods of teaching. We hypothesized that the addition of an interactive simulation exercise to standard training methods would increase the confidence of study coordinators. A simulation exercise was developed to replicate a complex clinical trial. Eighteen study coordinators completed pre- and postexercise confidence questionnaires. Questions were targeted at key trial components using a 0–10 scale (not confident to confident) and were categorized using Bloom's Taxonomy. The primary analysis compared overall mean pre- and postexercise responses. Secondary analyses assessed affective, psychomotor, and cognitive confidence. Significance was at $P < 0.05$. A significant increase in overall confidence (8.64 versus 5.77; $P < 0.0001$) was reproduced in the subcategory analyses (affective, 8.24 versus 4.89; $P < 0.0001$; cognitive, 8.75 versus 6.42; $P = 0.0003$; psychomotor, 8.63 versus 5.26; $P < 0.0001$). A high level of internal consistency and reliability in question responses within domains was observed, validating the questionnaire tool. In this preliminary report, we confirmed that addition of a simulation exercise to the training of study coordinators resulted in increased confidence. Simulation exercises should be considered when training study coordinators for clinical research trials.

(Anesth Analg 2004;99:●●●–●●●)

# Conclusions

- Important to understand goals for participation in multicenter trials (data access?, publication?, money?)
- Every Multicenter Trial is not the same
- Multicenter Trials can allow investigators to develop research infrastructure
- Success depends on planning and aggressive follow-through
- Develop role as thought leader to direct trial design and improve patient outcomes


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