Investigator Initiated Trials: Coordinator input for improved trial design and efficiency

Anna Parker

Manager, Anaesthesia, Perioperative and Pain Medicine Unit (APPMU), Melbourne Medical School

anna.parker@unimelb.edu.au

MACH Coordinator Workshop 22nd March 2017

Overview

Background:

- investigator initiated studies

The problem:

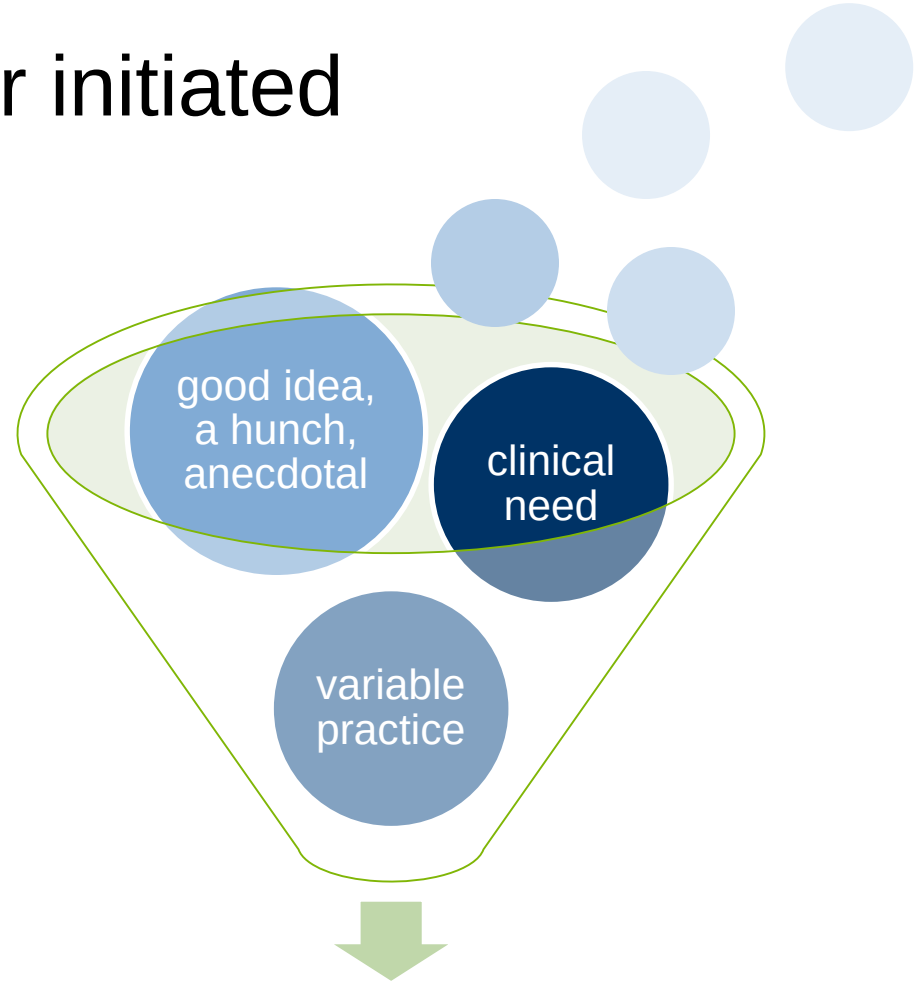
- study design complexity ↑
- study costs ↑

The solution?

- how can Coordinators add value?
- case studies and strategies

Background

Investigator initiated studies:



A range of possibilities

- Quality assurance
- Survey
- Observational study
- Single-centre
- Pilot study / feasibility
- Multicentre
- Large clinical trial

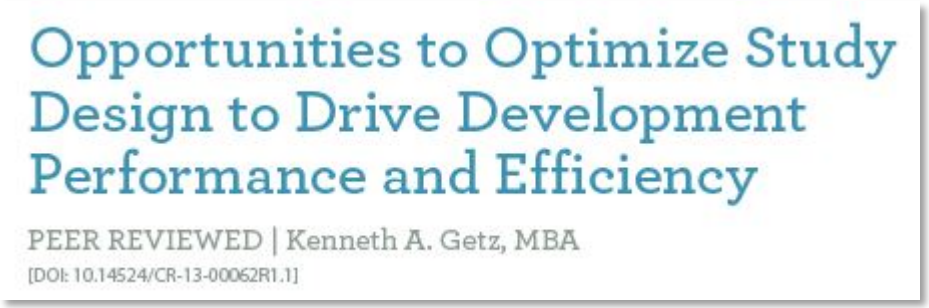
Research wrangling

Turning ideas into reality:

- Science
- Ethics
- Significance / innovation / need
- Team
- Resources
- Logistics

The problem

- Study design complexity rising steadily
  - number of protocol endpoints and objectives increasing
  - number of volunteer eligibility requirements
- More complex = more costly, slower, lower recruitment



"complex protocols are inversely related to recruitment and retention effectiveness and study cycle time"

The solution?

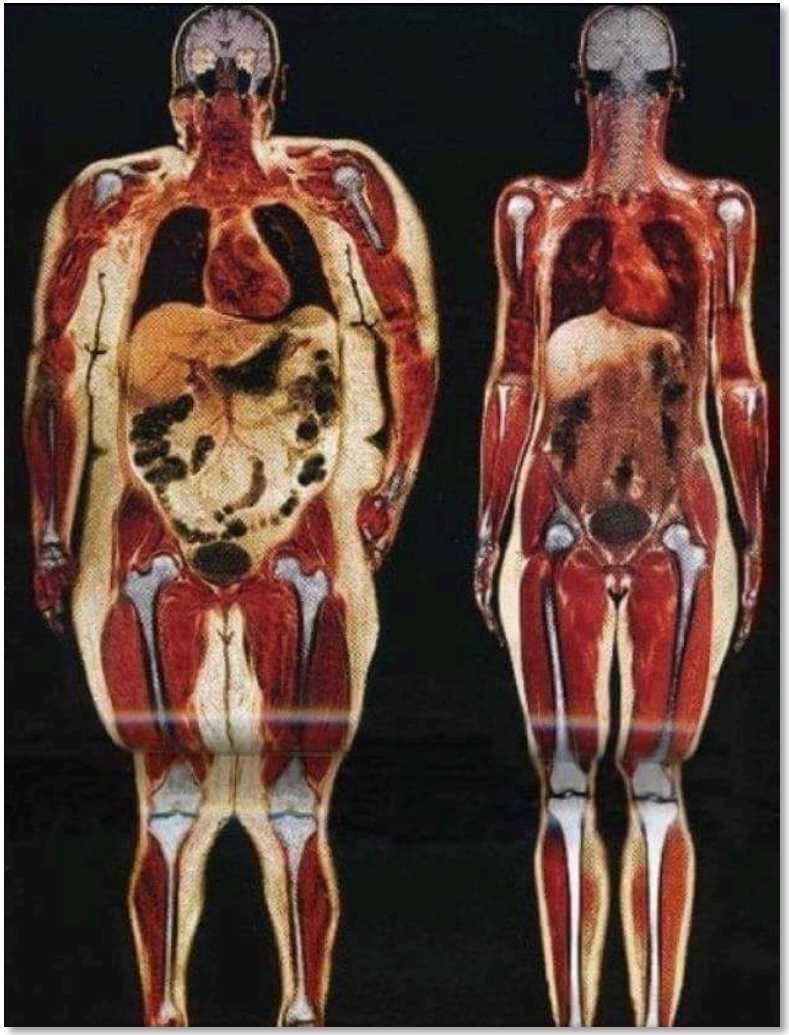
- evaluate protocol design practices
- look for ways to streamline and simplify
- make protocol more feasible from an operational point of view

"Whereas scientific objectives trumped all else in the past, operating objectives now carry substantially more weight."

*"[seek] feedback from principal investigators, **study coordinators**, and patients to identify areas where study design feasibility can be improved **prior to final approval of the protocol**"*

Case study 1: MUMSize Study

- Observational
- Collecting data from women having caesarean section
- 7 Unimelb hospital sites
- What sort of consent is feasible?
- Type of ethics submission?



Case study 1 cont.

Solutions:

- Verbal consent before, during or after C-section
- Colour coded CRF sections
- NMA review at Monash Health accepted by most sites

Case study 2: bad protocol, CRF

- Confusing or conflicting instructions
- Lack of clarity over definitions / endpoints
- Double handling, ie. WHODAS, transcribing data from one section to another

Case study 3:

Pilot study:

- Logistics…
- Drug of addiction
- Maintaining blinding
- Weekend follow-up
- Dose adjustment

Larger trial:

- Ensuring per patient payment covers screening time (25%)

Reduction Of Chronic Post-surgical Pain with Ketamine

Multicentre, double-blind, placebo controlled, Phase 3/4 randomised controlled trial of the effect of up to 72 hours of perioperative ketamine on the risk of development of chronic post-surgical pain.

5 years, 4,884 patients.

NHMRC 2017 $4.8 million

Case study 3 cont.

Protocol:

- SPIRIT guidelines
- Include definitions

eCRF:

- Reduce double handling

Tools for sites:

- Time saving templates

Challenges

- Workplace culture
- Convincing investigators of the value of your knowledge (more opportunity for input compared to sponsored studies)
- Taking time to optimise operational aspects early
- Removing the investigator/ coordinator divide
- Time, money/funding
- Use your network, share things that work

Benefits of Coordinator input

Coordinator input....	translates into:
Incorporating patient-centred viewpoints	• improved participant satisfaction • meaningful, patient-centred endpoints
Streamline CRFs and other trial processes	• decrease incidence of errors • remove double handling • less wasted time, frustration
Effective resource and logistics planning	• saves time, money, • gets everyone on board, cooperating, enthusiastic • increased recruitment

Research Equity for CALD and Indigenous Patients through eHealth Participant Information

- How can we recruit more culturally and linguistically diverse patients?
- Up to 50% of our patients excluded due to language/cultural issues
- Looking for Coordinators to provide feedback on prototype app
- 30 minutes of your time, at your convenience

An invitation…

- Ideas?
- Something that could work better?
- Let's work together and increase Coordinator-led research across the network

Thank you

Anna Parker

Manager, Anaesthesia, Perioperative and Pain Medicine Unit (APPMU), Melbourne Medical School

anna.parker@unimelb.edu.au