



(Trial) Forging Core Outcome Sets: Trials methodology COS and insights for implementation

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What is an efficient trial?

- **Scientific efficiency:** right question, right design
- **Process efficiency:** do what is needed to answer question, keeps focused, results made public in a way people can understand

Let's do what we did last time..

- **'There is a peculiar paradox that exists in trial execution - we perform clinical trials to generate evidence to improve patient outcomes; however, we conduct clinical trials like anecdotal medicine: we do what we think works we rely on experience and judgement and.....limited data to support best practices.'**



A systematic approach to making trials more efficient

The evidence base for how to make the trials process efficient is remarkably thin. Trial Forge aims to change this.

EXPLORE PATHWAY

LEARN MORE



Trials

Randomised controlled trials are the gold standard for evaluating healthcare



Essential

Randomised trials are the cornerstone of evidence-based healthcare because they



Inefficient

The evidence base for how to make the trials process efficient is remarkably thin.

Methods priorities

- 1. Recruitment**
- 2. Choosing what to measure**
- 3. Retention**

Informed consent to trials: what is the problem?

Nishimura et al. *BMC Medical Ethics* 2013, 14:28
<http://www.biomedcentral.com/1472-6939/14/28>

 BMC Medical Ethics


RESEARCH ARTICLE **Open Access**


Improving understanding in the research informed consent process: a systematic review of 5 interventions tested in randomized controlled trials

Adam Nishimura¹, Jantey Carey^{2,4}, Patricia J Erwin², Jon C Tilburt^{2,3,5}, M Hassan Murad^{2,3,4} and Jennifer B McCormick^{2,3,5*}

Audio-visual presentation of information for informed consent for participation in clinical trials (Review)

Synnot A, Ryan R, Prictor M, Fetherstonhaugh D, Parker B



 **Cochrane Library**
Cochrane Database of Systematic Reviews

Decision aids for people considering taking part in clinical trials (Review)

Gillies K, Cotton SC, Brehaut JC, Politi MC, Skea Z

ELICIT: EvaLuation of Interventions for informed Consent for randomIised controlled Trials

Gillies *et al. Trials* (2015) 16:484
DOI 10.1186/s13063-015-1011-8



STUDY PROTOCOL

Open Access

Evaluation of interventions for informed consent for randomised controlled trials (ELICIT): protocol for a systematic review of the literature and identification of a core outcome set using a Delphi survey



Katie Gillies^{1*}, Vikki Entwistle¹, Shaun P. Treweek¹, Cynthia Fraser¹, Paula R. Williamson² and Marion K. Campbell¹



ELICIT Outcomes

- **149 papers included**
- **1006 verbatim outcomes**
- **~40 individual outcomes**
- **Range of outcomes reported 1-35**

ELICIT Outcomes

Informedness

Informed consent

Knowledge

Awareness

Retention of information

Recall

Comprehension

Understanding

Therapeutic Misconception

Equipoise

Health literacy

Decision making attributes

Anxiety

Satisfaction

Confidence

Experience

Attitudes

Expectations

Trust

Beliefs

Perception

Relationships

Decisional conflict

Decision regret

Values of the participant

Behaviour

Recruitment

Willingness to participate

Previous involvement in research

Consider participating in future trials

Attrition

Protection

Rights

Autonomy

Non-maleficence

Voluntariness

Beneficence

Justice

Insights for implementation

- **Methodology 'guidelines'**
- **Incorporation and promotion of COS through appropriate platforms**
- **Buy in from funders**

Summary

- **Much of the business of doing trials is not very efficient**
- **Core outcome sets can improve trial methodology efficiency**
- **Implementation from both a top down and bottom up approach**

Thank you!



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<http://trialforge.org>