

# Publication of Study Results: *Exercises in Damnation?*

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**Ross Baldessarini:** *Moderator*

*Speakers:*

**Ramy Mahmoud:** *Janssen*

**Atul Pande:** *Pfizer-CNS*

*Panelists:*

**Joseph Coyle:** *Arch Gen Psychiatry*

**Dilip Jeste:** *Am J Geriatr Psychiatry*

**Henry Nasrallah:** *Schizophrenia Res*

**Bjorn Olsen:** *J Neg Results Biomed*

**André Picard:** *Toronto Globe & Mail*

*...Current clinical research relies on a methodology that is readily open to abuse. The mechanics of large-scale randomized trials are highly complex, the data opaque, and the results marginal—all features that prevent a clear view of any research misconduct. Moreover, the absence of any method to confirm or refute the results means that such behavior is likely to go undetected...Tinkering with new rules...will do little to improve the reliability of the results of clinical trials. What is needed is a complete reappraisal...*

**James Penston, MD, Consulting Physician**  
**BMJ 1995; 330: 421. [2/19/05]**

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## *Issues for Consideration: I*

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- Why is reporting trials methods & results so at-issue?
  - Clarify stakes for: clinicians, academics, industry, FDA/government, citizens, & research subjects
  - Are data OK for efficacy-licensing adequate for safety?
  - Is reporting of clinical research adequate now?
  - How can it be improved?
  - Are trials-registries necessary, effective, feasible, or credible?; who monitors & who pays?
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## *Issues for Consideration: II*

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- **Who owns & controls protocols & trials data?**
  - **US Pharma: Risk of becoming a regulated public utility?...or worse?**
  - **Can journal editors help? Part of the problem? Key to a solution?**
  - **Will journals accept negative reports of sometimes unknowable quality?**
  - **How can the news media help?**
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## *Issues for Consideration: III*

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- What are “negative” results: for efficacy?, effectiveness?, safety?
  - Is biased reporting of “positive” results unique to drug trials?
  - Should we abandon hypothesis-testing & p-values?
  - Is it time to give up LOCF?, discontinuation trials?, placebos?
  - Can better trials designs and analyses help?
  - Can regulatory standards be modernized?
  - How to detect infrequent adverse events & who pays?
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