

An Industry Perspective on COI

Manage or Eliminate?

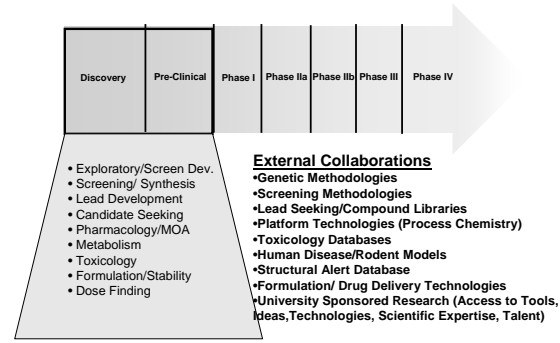
...can we treat the (presumptive) illness without killing the patient?

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 PRIM&R: May 3, 2004

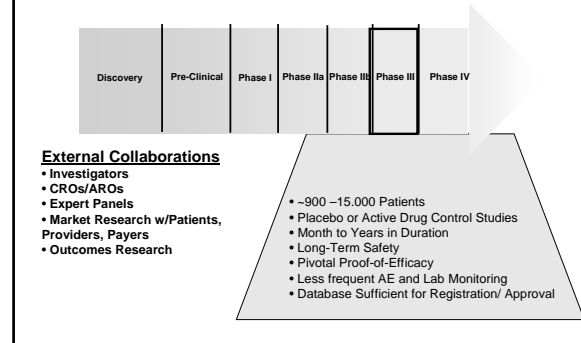
Pharmaceutical Research is Multifaceted, Complex, and tests the boundaries of current knowledge...

- ◆ Occurs across the lifecycle of a medicine
 - From discovery through patent expiration
- ◆ Internally: uses a team-based approach; with matrixed internal functions
- ◆ But, no matter how well staffed...
- ◆ **Collaboration with external partners is critical throughout the process, from idea generation through partnership on clinical studies, to marketing strategies**

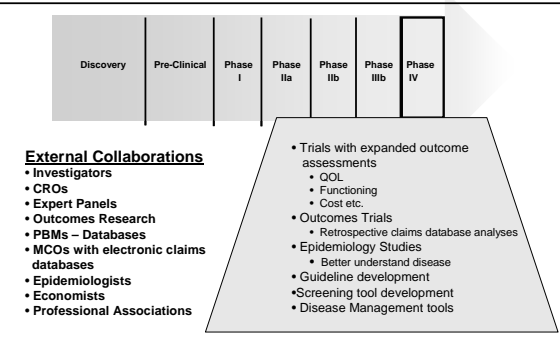
DISCOVERY & PRE-CLINICAL PHASE



PHASE III – Full Development



PHASE IV – Outcomes Research



Beyond Phase IV: Independent Research Grants (IRGs)

- ◆ Another mechanism to better elucidate efficacy and safety of our medicines; work with academic and non-academic collaborators on areas of mutual interest
- ◆ Investigators request funding, often through Regional Medical Research Specialists
- ◆ Reviewed at HQ; approved grants are conducted independently by investigator from protocol through execution
- ◆ Grant requests may include clinical, outcomes or epidemiological studies, development of screening tools, guidelines, etc
- ◆ Potential COI's in disseminating results managed through multiple sets of guidelines

Example: Research Conflicts...

- ◆ ... an investigator's interest in career advancement, although entirely ethical and appropriate in itself, may conflict, or appear to conflict, with the interest of subjects in minimizing the risk of psychological harm, physical injury, or death.
- ◆ The potential...conflict between the personal interests of investigators and those of subjects is inherent in all research involving human subjects...
- ◆ The conflict cannot be prevented or eliminated, but its existence must be recognized if the risk to research subjects is to be minimized.
- ◆ The question is how to deal with such conflicts

Norman Levinsky NEJM 347:10 9/05/2002 pg 760

Ethical Issues-Access Restrictions & Ethics

- ◆ QI ...often is tied to cost-containment efforts
- ◆ QI...may be categorized as research
- ◆ QI may not be of benefit to the patient and may...represent a potential burden or risk...as such may qualify as research
- ◆ If such QI research is done without patient knowledge or consent with a possibility of harm, it may then be considered to be a violation of the Nuremberg Code.

Kofke & Rie Critical Care Medicine 2003 31:3 (suppl.)

COI-in the 'real world'...

- ◆ Boston Globe 06/09/2003...
Harvard may ease rules on faculty ties to drug firms
 - ◆ Limits: <\$20K Stock; <\$10K Consulting Fees
"There are people who are very unhappy"
Assistant Dean Margaret Dale
 - ◆ Pro: "We have to think creatively and flexibly about how to work with the private sector...how to make sure research moves from bench to bedside" L. Summers
 - ◆ Con: "Harvard would be unwise to loosen its restrictions...it should tighten them" M. Angell
- "Should you have equity in a product you're testing...the answer should be no." G. Annas

COIs: plan, provider, patient...Health Care COIs Ubiquitous

The Wall Street Journal, March 20th 2002 (H. Jenkins)
" All professionals face intrinsic conflicts of interest in their work.: Dealing with them responsibly is what makes them professionals"

Archives of Internal Medicine, March 25th 2002
J. Alpert MD, S. Furman MD, L. Smaha MD
" Every individual in our society has some potential involvement that might lead to a conflict of interest situation. We are all motivated by self-interest and prone to bias."

Cannot eliminate/Must manage

Hypotheses...

It is in the interest of Society and individuals that the best expertise be available to profit driven, private sector firms in the life sciences. In these interactions conflicts of interest are inevitable and must be managed.

Barring interactions based upon identified and potential conflicts of interest incurs (potentially) hidden costs in technologies undeveloped and safety/efficacy issues unaddressed

COI-A Case Study-Virtual vs. Optical Colonoscopy

Dr. X and spouse, Dr. Z, Radiologist in Practice

Issue: WSJ Report on Efficacy of Virtual Procedure

- 1) Dr. X notes + results of V. Colonoscopy in WSJ; suggests spouse consider adding procedure to practice (=Financial COI)
- 2) Dr. Z Considers idea, weighs income potential vs. time and 'tediousness' of reviewing multiple images (= Financial COI)
- 3) Dr. Z Considers 'costs' of internecine struggle with GI staff (=Professional COI)
- 4) Dr. Z Considers costs of equipment required to perform procedure and potential other uses of same (= financial COI)
- 5) Dr. X points out potential liability risk of procedure since there is a permanent record and misses are inevitable (= liability COI)

Conclusion: NOT A GOOD IDEA

Note: The drivers of this decision, a case of multiple COIs?