

Collaboration between Academia and Industry

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What is “collaboration?”

- Industry has short- and long-term needs (mission-oriented).
- Short-term: How to deal with specific analytic issues from a clinical program?
- Long-term: For example, how to choose “estimand for clinical studies?” The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (**ICH-E9**)?
- **Professor Don Berry: Clinical trial methodology research is now led by industry and regulatory agencies. The academia is not a major player anymore.**

Back in the old days

- Partnership between industry and academia:
- Harvard had quite a few of partnerships: Schering-Plough, Weyth, Pfizer, Alkermes, Merck et al.
- No strings attached (no specific deliverable requirements)

- No more “gifts” from industry to academia
- University has a rigid conflict interest rule about “deliverable”
- It is very difficult to get a “grant” from industry for analytic research.
- US NIH puts more research money on bioinformatics and computation biology, very little on the clinical trial late stage method research.

Collaboration via Consultation

- Industry initiates the conversation.
- Most are time sensitive issues, need to solve the problems in a short time period. Generally, university is not interested in such consultation activities.
- The following are examples for aiming relatively long-term projects via personal connections:

Circulation: Cardiovascular Quality and Outcomes (May 2019)

Integrating Data From Randomized Controlled Trials and Observational Studies to Assess Survival in Rare Diseases Insights From Pulmonary Arterial Hypertension

CONCLUSIONS: These analyses show that, in a rare disease, real-world observational data can complement randomized controlled trial data to overcome some challenges associated with assessing survival in the setting of a randomized controlled trial.

American Heart Journal, Sept 2019

Restricted mean survival time for the analysis of cardiovascular outcome trials assessing non-inferiority: Case studies from antihyperglycemic drug development

Cardiac Safety Research Consortium

JAMA Oncology, June 2018

**Evaluating Treatment Effect Based on Duration of Response for a
Comparative Oncology Study**

How can the academia work with industry?

- Need more young people interested in clinical trial method research.
- Need more research funding.
- May create satellite companies “around” university so we can “deliver” the final products.
- NISS can play an important role.