

# The Methodological Challenges

- ▣ Need long term follow-up, both in risk studies and in RCTs.
  - Cost too much. Take too much time.
  - Problems of “sporadic” funding.
- ▣ Even when funded, success rate is low.
  - Non-random dropouts, missing data, treatment switches, changing measures, changing research priorities.
- ▣ Populations of interest heterogeneous: One size does not fit all!
- ▣ Answers gained in research studies not directly relevant to the questions clinicians and policy makers need to address clinical needs.

# What we might do differently...?

- ▣ Focus on meaningful effect sizes, not on p-values.
- ▣ Articulate research questions clinicians/policy makers need answers to.
- ▣ Explore for moderators and for mediators
  - Sequential RCTs.
- ▣ Use Accelerated Lifetime designs.
- ▣ Consequences:
  - Will have greater impact on patient care.
  - Will increase the effect sizes, thus reduce the necessary sample size, thus the cost.
  - Answers would be more swiftly reached.