An Academic Research Perspective

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Clinical Researchers Have Choices

- Database observational studies
  - Dependent on statistical colleagues
  - Need to be comfortable with data that are less precise
  - Not easy to investigate biological pathways
  - Relatively short time from inception to completion
  - Less regulated (clinicaltrials.gov registration, need to publish all results)

Clinical Researchers Have Choices

- Standard Randomized Clinical Trials
  - Need commitment to recruitment and data collection
  - May include investigation of biological pathways
  - Highly regulated
  - Analysis relatively uncomplicated
  - Conclusions high impact

Who is the target for research report?

- Different stakeholders – regulators, payers, clinicians, patients
- Observational methods much more difficult to explain than usual randomized clinical trial

    Has anyone changed practice because they thought the propensity matching was outstanding
- Health systems tempted to make decisions based on their own data

Clinical Researchers Have Choices

- Innovative clinical trial designs like pragmatic designs or cluster randomized designs
  - Need to get cooperation of health system and health care providers
  - Need to incorporate EMR-IT data sources
  - If cluster design without required consent, conduct of study can be relatively easy
  - Analysis more complicated than standard randomized clinical trial