



# An Insurer's View: Paying for Clinical Trials

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## ➔ ***Why do insurers exclude trials by using the “experimental” phrase?***

- Originally a way to prevent quackery coverage
- Evolved to exclude therapy not based in evidence
- The irony—trials provide the evidence!

Newcomer LN. Defining Experimental Therapy: A Third Party Payer’s Dilemma. NEJM 1990; 323:1702-4

- Provides the evidence for future decisions
- Patient receives protocol driven care
- Informed consent
  - § Better understanding of intent
  - § Better understanding of potential risks

- Legal
  - § Definitions
  - § Scope
  - § Precedent for coverage
- Cost effectiveness analysis
  - § Particularly relevant for Phase III trials
- “Me, too” trials
  - § Duplication
  - § Conflict of interest with academic promotion pathways

*Researchers must stand with payers to defend against off trial therapy*

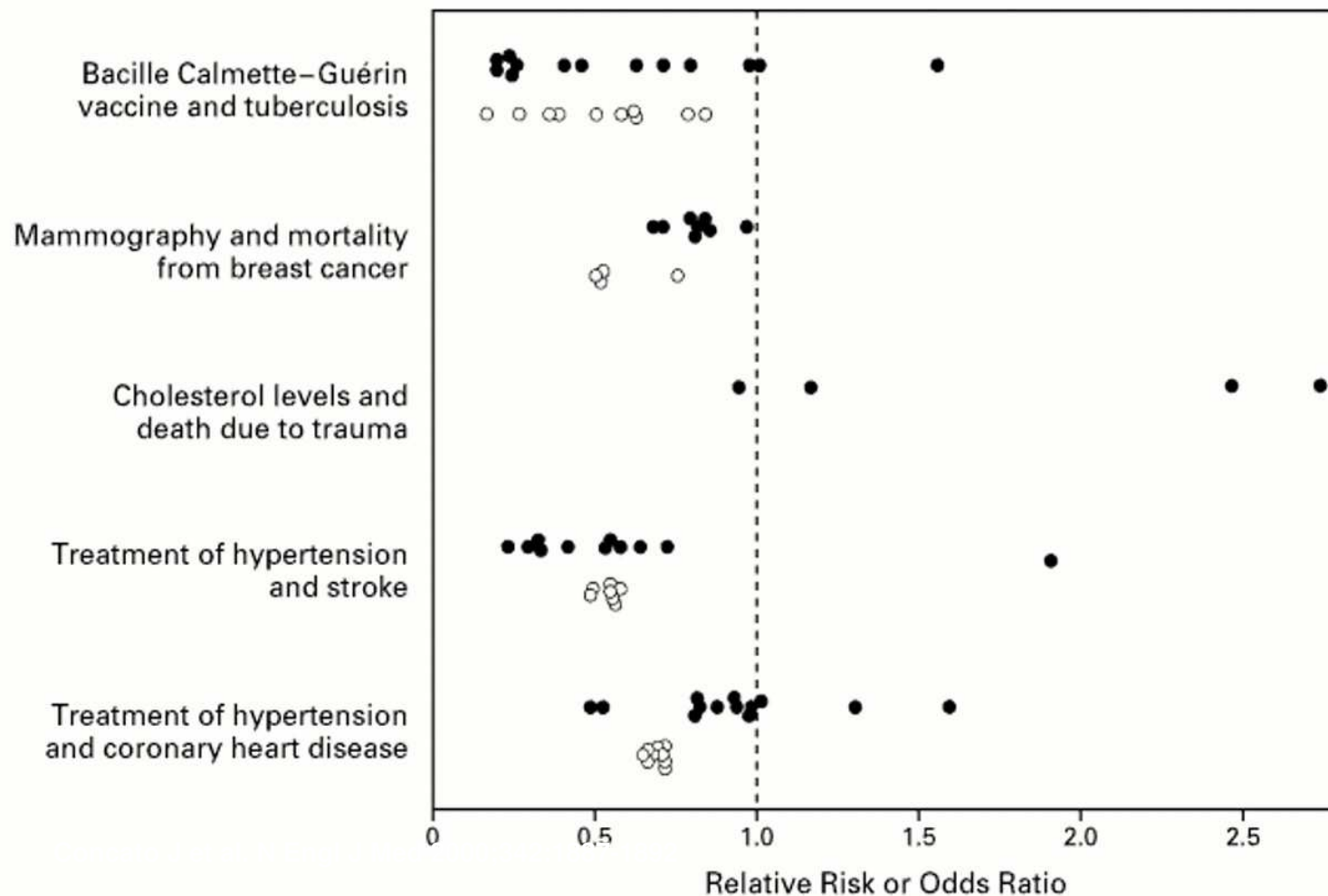
- New “off label” indications
  - § Manufacturer already making a profit from the product
- Opportunity costs
  - § Trade off between affordability and coverage
  - § Premium estimates \$0.93 PMPM
- Real life patients versus Superman subjects
  - § Understanding realistic responses

## ***The Tyranny of the Randomized Controlled Trial***

- Tightly controlled observational studies can produce meaningful results
- Higher patient accrual
- Allows diverse opinions without compromise
- Less expensive

*How can we  
maximize the value  
of the dollars we  
spend on trials?*

# Observational Comparisons Work



NEJM 2000: 342; 1887

## ***Accountable Research***

- Eliminate duplication
- Require novel approaches
- Penalty for failure to accrue patients
- Mandatory publication of negative trials
- Exclude “local” trials from coverage
  - § New Jersey law shields researchers from accountability

*How can we  
maximize the value  
of the dollars we  
spend on trials?*

- Payment
  - § Identification of trial enrollees
  - § Identification of experimental component of trial
- Mosaics
  - § Products
  - § State regulations
  - § Employer plans
- Which trials qualify?

## *Which trials qualify?*

- ***National Institutes of Health (NIH). (Includes National Cancer Institute (NCI).)***
- ***Centers for Disease Control and Prevention (CDC).***
- ***Agency for Healthcare Research and Quality (AHRQ).***
- ***Centers for Medicare and Medicaid Services (CMS).***
- ***Department of Defense (DOD).***
- ***Veterans Administration (VA).***

*Employers have  
the option of  
purchasing this  
coverage*

## ***Coverage is Possible***

- Benefits are real for both parties
- Both perspectives need to be understood and acknowledged
- The funds are limited, so hard choices will have to be made

***Collaboration  
requires  
accountability***