THE TRIAL REPORTING SYSTEM
(view from 30,000 feet)

IPD Sharing
- Provides audit trail for summary results reporting
- Enables re-analyses of trial data
- Enables combining of trial data with other data for novel investigations

Summary Results Reporting
- Provides “minimum results reporting set” for each trial based on registered protocol information
- Structured data enable accurate search and retrieval based on elements of study design

Prospective Registration
- Documents existence and enables tracking of ongoing and completed trials
- Allows verification of key protocol information and tracking of changes
- Provides survey of research landscape (e.g., by topic or across the clinical research enterprise

IPD Sharing in Context

• Trial registration provides the foundation
  • List of ongoing and completed trials
  • Key protocol details and ability to track progress
  • Searchable

• Summary results reporting to ClinicalTrials.gov
  • “Minimum reporting set” for each trial
  • Structured system facilitates quality control
  • Objective information, limited narrative text
  • Study protocol and SAP

• IPD Sharing
IPD Sharing—need for precision:

• What is meant by "data"?
  • Degree of “rawness” affects theoretical benefits and risks
    • E.g., Case report forms vs. coded, analyzable data sets
    • Type, quality and usability of meta-data?

• What is meant by “sharing”?
  • Involvement of original research team, or not?
  • Latent vs. Active?
    • Actual value of enabling third party use of data for scientific purposes
    • Is there scientific value in ensuring that all trials are at risk for audit?
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### POSSIBLE GOALS OF TRIAL REPORTING?

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Trial Reporting Stats from ClinicalTrials.gov

- Most trials appear to be registered
  - About 1/3 registered late
- 50% (?) trials report results (including publication)
  - A bit higher for those under FDAAA
  - Varies by sector (industry better than academia)
- Very few trial records have links to IPD
  - E.g., of 4719 trials completed in 2016 (site in US):
    - 5 links to IPD
    - 2/1957 drug studies (phase 2, 3 or 4) have links to IPD
    - Overall: 653 studies with links to IPD (denominator?)
- Intention to share IPD? Of 7309 trials starting in 2019 (site in US)
  - 1120 YES (15%); 3749 NO; 2440 Undecided or Missing
ACTUAL STATUS OF TRIAL REPORTING

IPD Sharing

SUMMARY
RESULTS
REPORTING

TRIAL REGISTRATION
For consideration:

• Must keep our eyes on the ball: registration and summary results reporting are key to the Evidence Base

• Searchability through public systems is essential: without this, new kind of reporting bias will be introduced

• What are the goals?
  • Low burden of posting and using IPD?
  • Certain # or % of trials with IPD available?
  • Culture in which all trials are “at risk” of audit?
  • High impact “discovery” from use of IPD?

• What might prompt a mid-course change of direction?