IPD SHARING IN CONTEXT

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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?

IPD SHARING

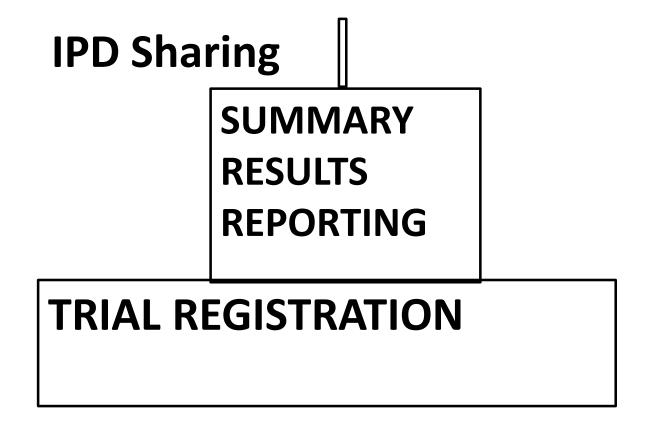
SUMMARY RESULTS REPORTING

TRIAL REGISTRATION

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



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?