IPD SHARING IN CONTEXT

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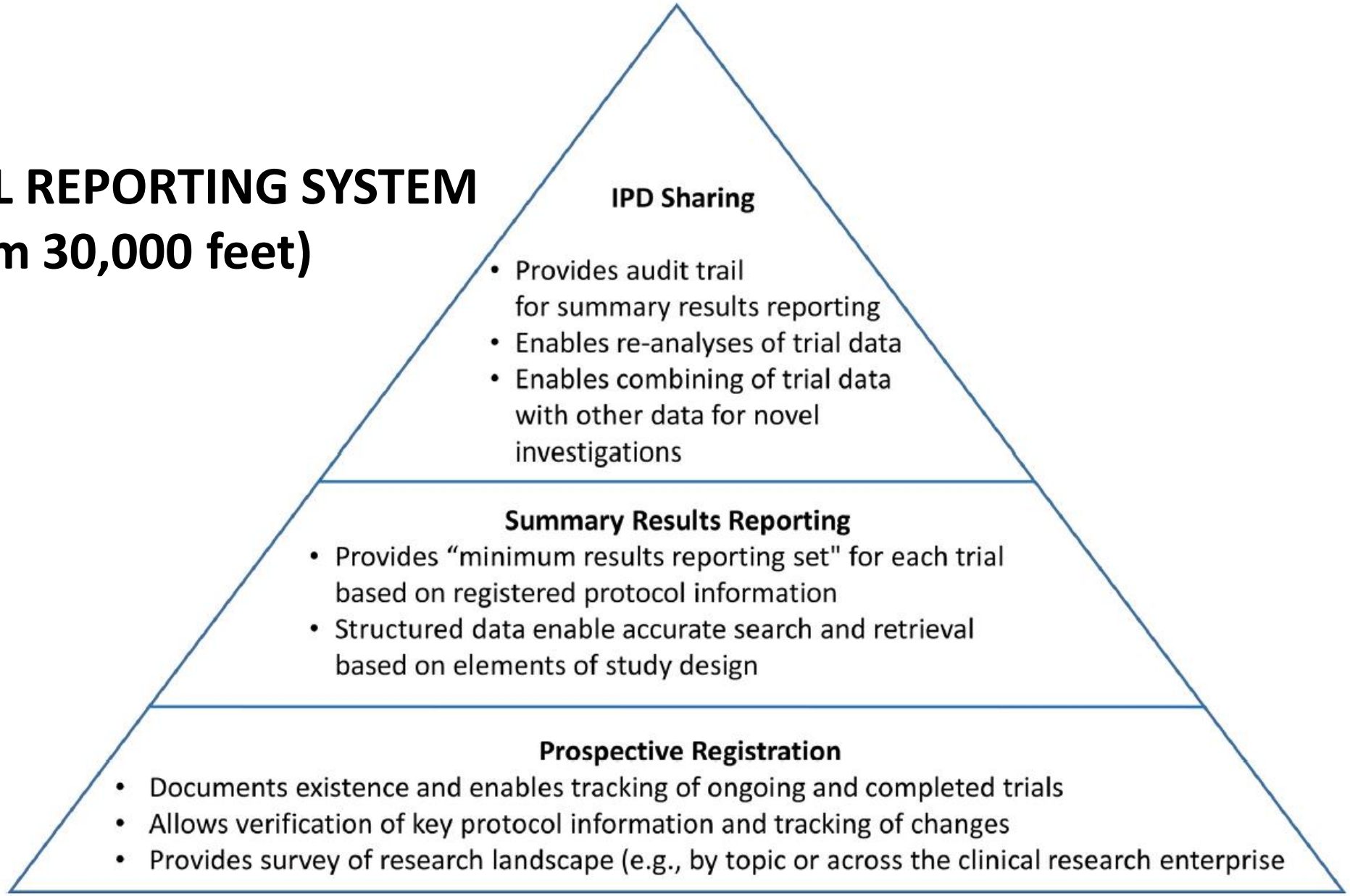
THE TRIAL REPORTING SYSTEM (view from 30,000 feet)



Source: Zarin DA, Tse T. *PLoS Med*. 2016 Jan 19;13(1):e1001946.

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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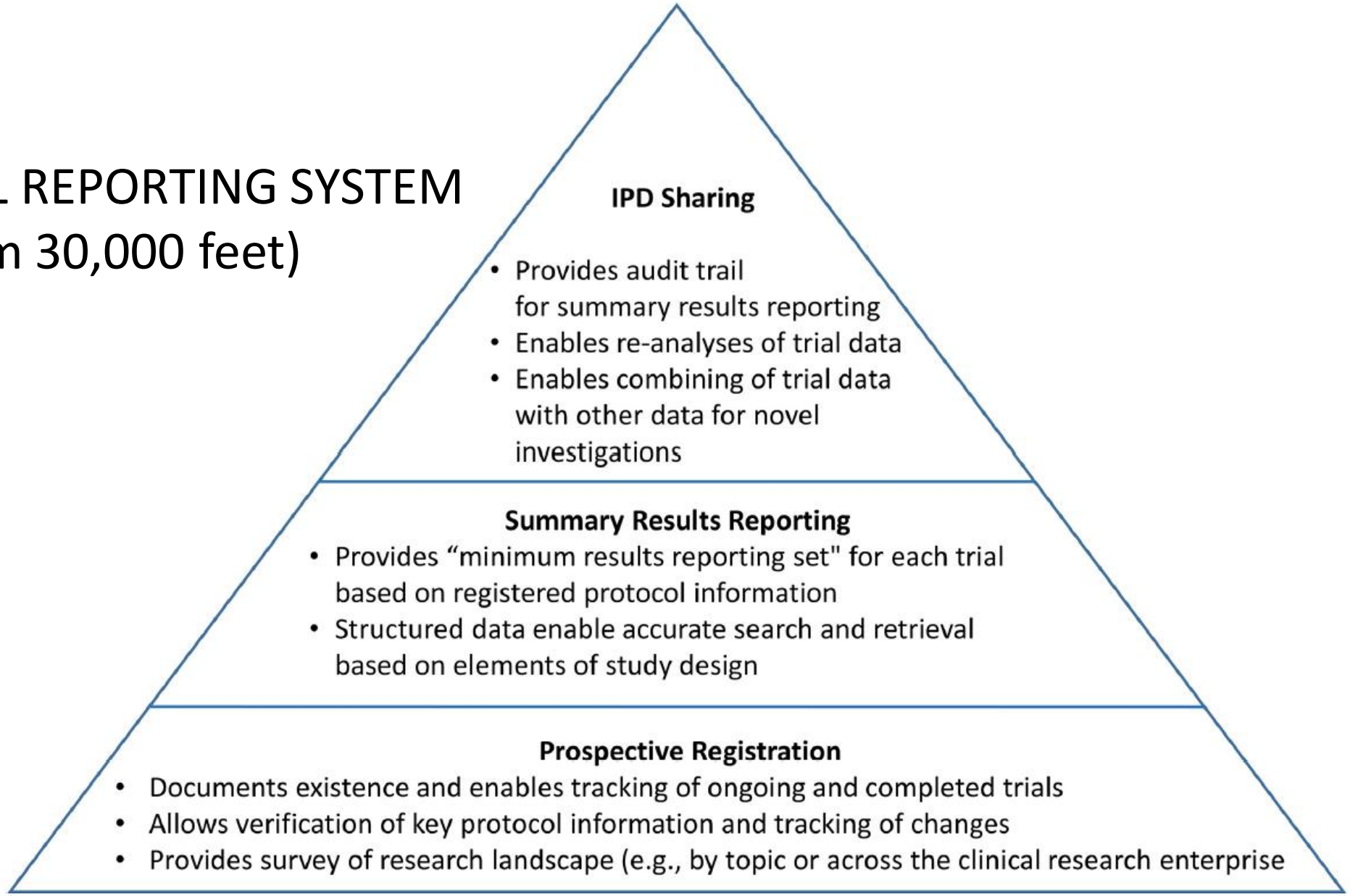

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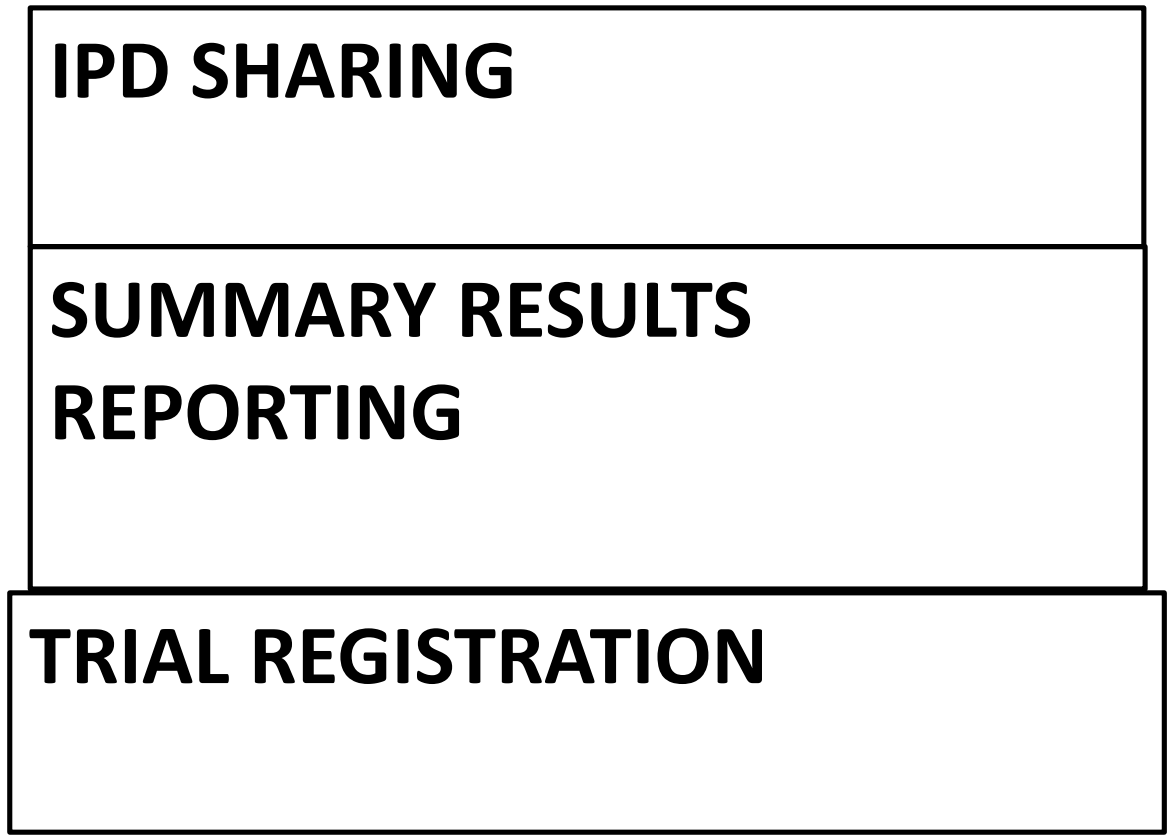
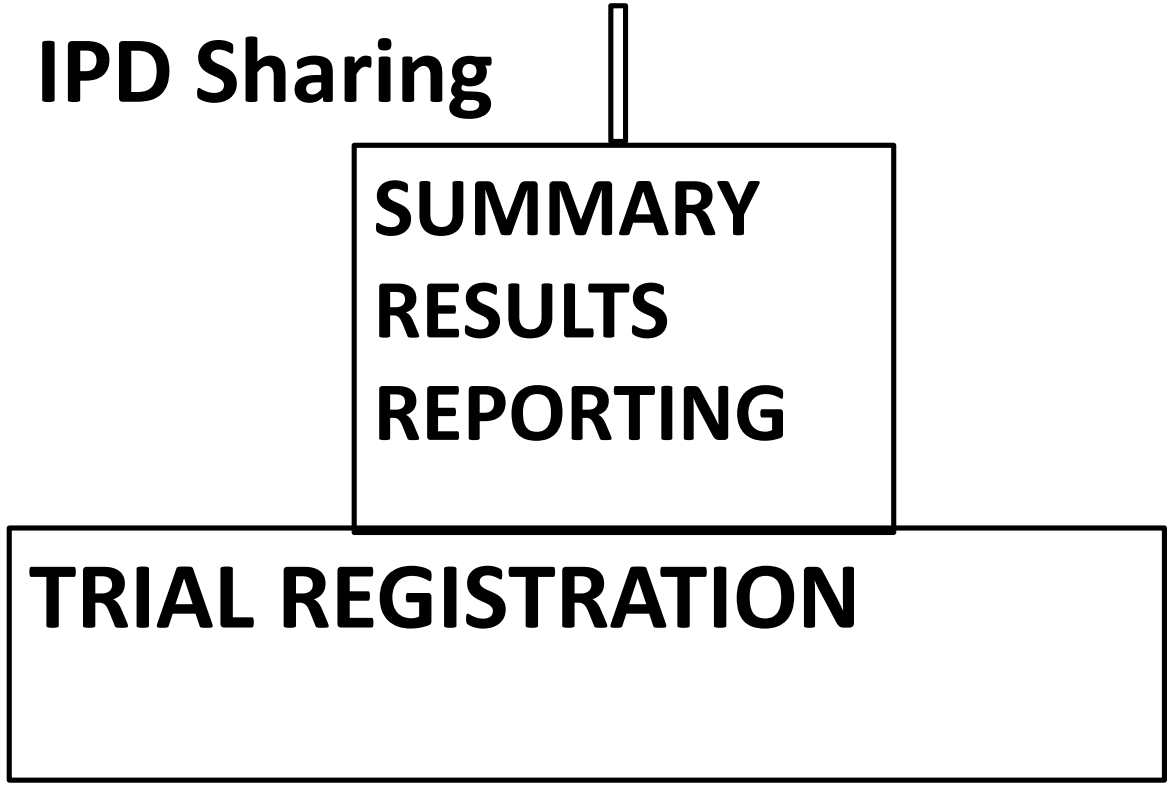
POSSIBLE GOALS OF TRIAL REPORTING?



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?