

**Title:** Clinical trial data sharing in the 21<sup>st</sup> century: a scoping review of the literature, IMPACT (IMProving Access to Clinical Trial data) Observatory

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**Cochrane relevance/category:** knowledge translation and increasing the quality of systematic reviews and reliability of evidence

**Keywords:** transition in clinical trials, data sharing, initiatives, policy, evidence

**Background:** There is increasing understanding of the importance of reanalysis of raw data for advancement of science, reducing research waste, and increasing the reliability of evidence gained by systematic reviews of clinical trials (CTs). The IMPACT Observatory is assessing transitions of CTs regarding data sharing.

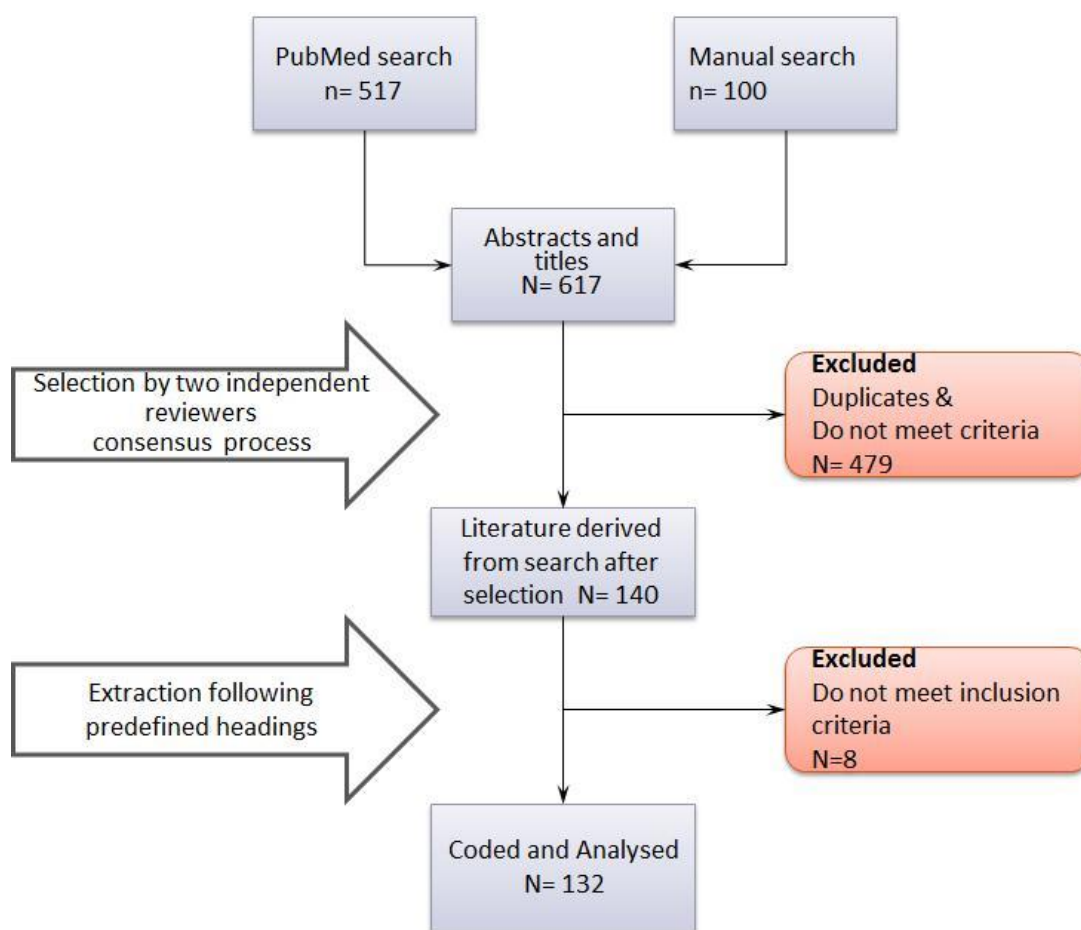
**Objectives:** Present the preliminary results of a scoping review of the literature aiming to assess the dynamics of CT data transparency and related changes of culture, policies and practice since the baseline set in 2000.

**Methods:** A scoping review of the literature consists of a search, selection, and analysis of publications. Following independent analysis of the manual and PubMed search results, two reviewers applied a consensus process to select papers that meet our criteria (Fig.1). Relevant information was extracted in Excel using predefined headings. Two reviewers coded and analyzed them and solved eventual disagreements by discussion.

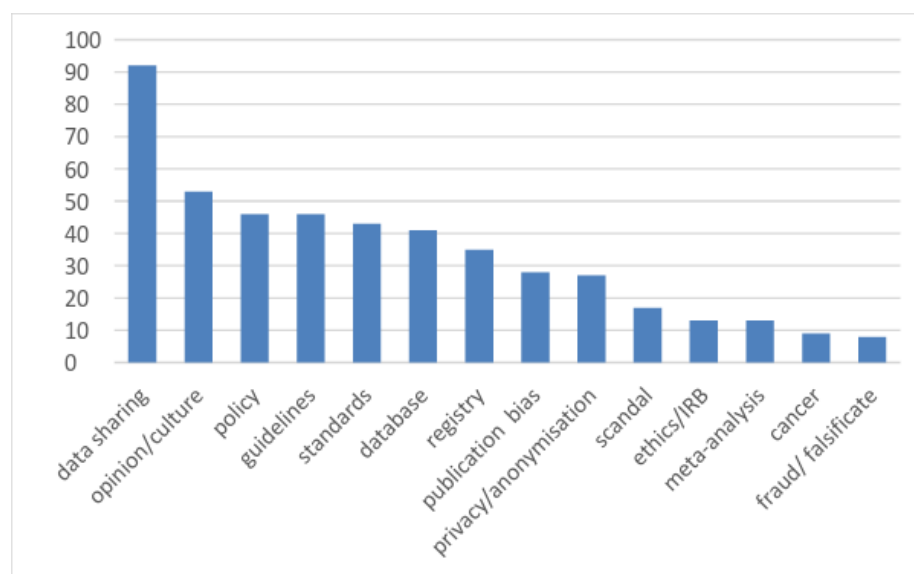
**Results:** In the analysis of 132 selected papers we mapped the changes in CT data sharing since 2000. The focus of the scientific community evolved from publication bias over protocol disclosure to sharing of aggregate and raw data and forming databases and registries with open access. Data sharing, culture, guidelines, standards, policies, and databases are the main topics discussed (Fig. 2). The lack of methods and standards of data sharing are identified as the main gaps. Players include journal editors, publishers, researchers, funders, pharmaceutical industry, media, consumers, and regulators. Numerous events, including court cases, scandals, initiatives and projects influenced data sharing and CT enterprise.

**Conclusions:** Since the year 2000, we have witnessed important initiatives by numerous stakeholders aimed at improving the quality of evidence and reducing research waste by broader sharing and reuse of CT data. However, there are obstacles to overcome and gaps to fill including changing the research culture and developing methods and standards for data sharing.

**Figure 1:** Scoping review of literature, search, selection, extraction, and analysis; adapted Consort flow diagram



**Figure 2:** Frequency of topics discussed in the literature published since 2001; a scoping review of the literature on clinical trial data sharing; preliminary results



*Note:* Several topics are sometimes discussed in the same paper