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Health Care Systems Research Collaboratory

Reporting ePCT Results

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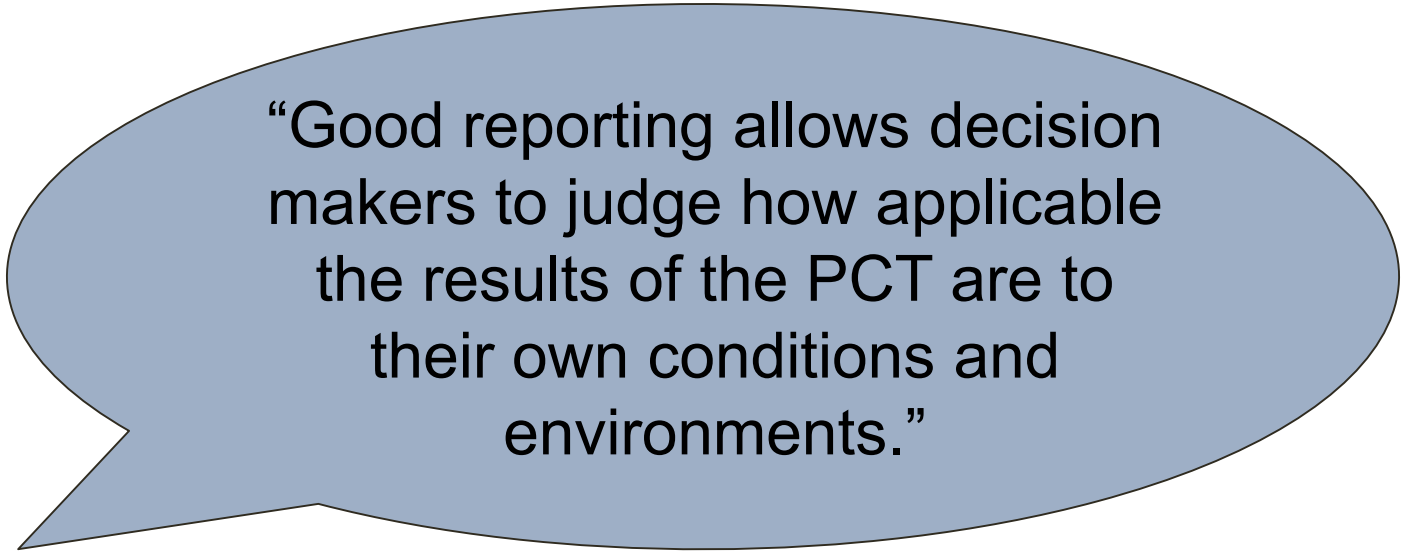
Goal of transparent reporting



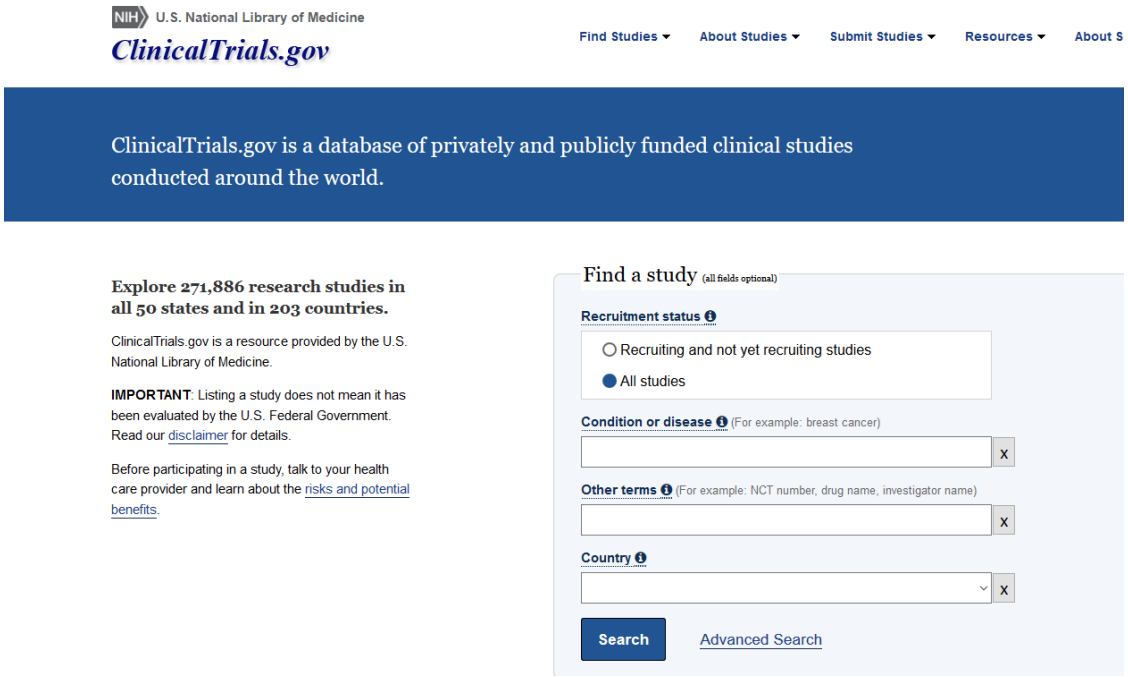
From the *Living Textbook* chapter on dissemination approaches

Guidance on what to report

- ClinicalTrials.gov
- CONSORT (2010)
  - Pragmatic trials extension (2008)
  - Cluster trials extension (2012)
  - PRO extension (2013)
  - Pilot & Feasibility (2016)
- NIH Collaboratory PCT Reporting Template
  - Special considerations for reporting embedded pragmatic trials
  - Available on the *Living Textbook* (and in your meeting materials)
- *Living Textbook* chapters on dissemination: experience from the Demonstration Projects

ClinicalTrials.gov

Requirement: Register clinical trials & report key data about the trial design, study population & outcomes



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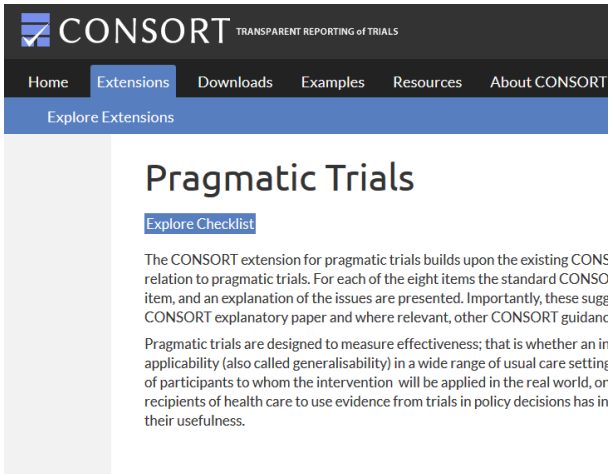
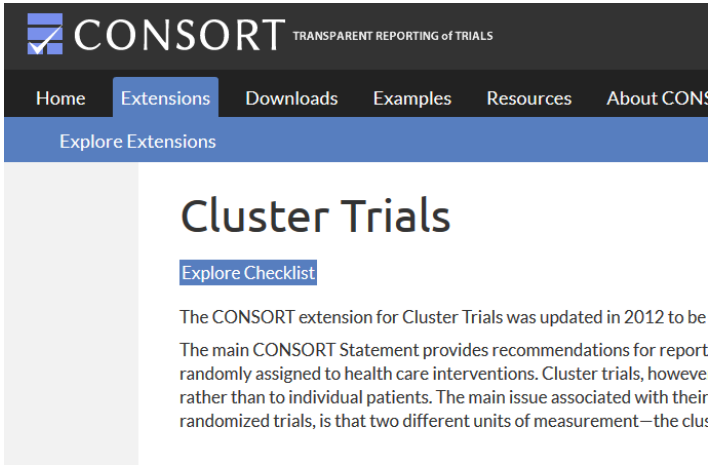
CONSORT

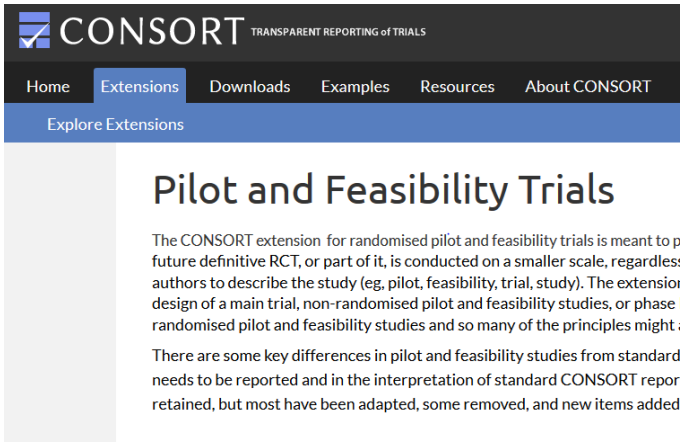
- Evidence-based, minimum set of recommendations for reporting randomized trials
- Standard way for authors to prepare reports of trial findings
- Facilitates complete & transparent reporting
- Aids in critical appraisal & interpretation

www.consort-statement.org/

CONSORT extensions







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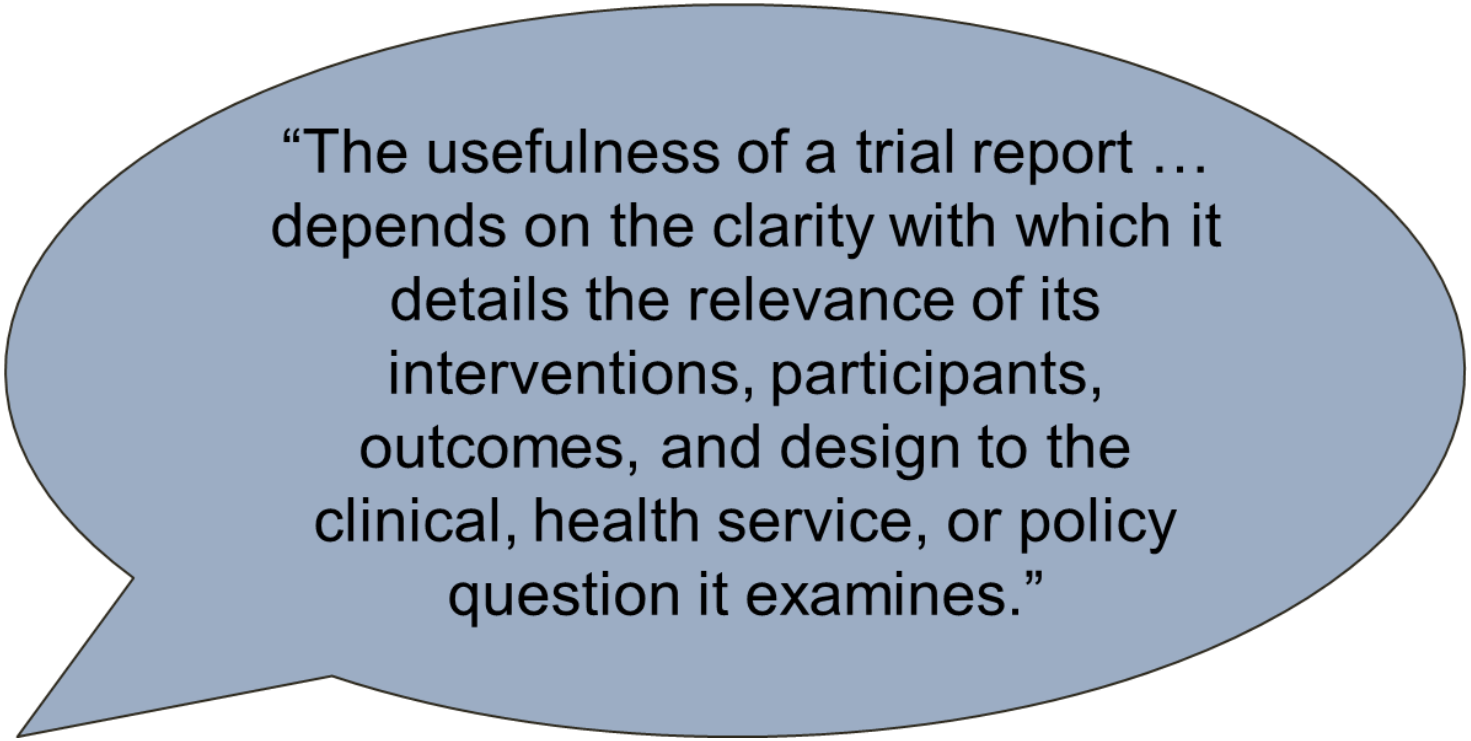
CONSORT pragmatic trial extension



From authors of the CONSORT Pragmatic Trial extension (Zwarenstein et al., 2008)

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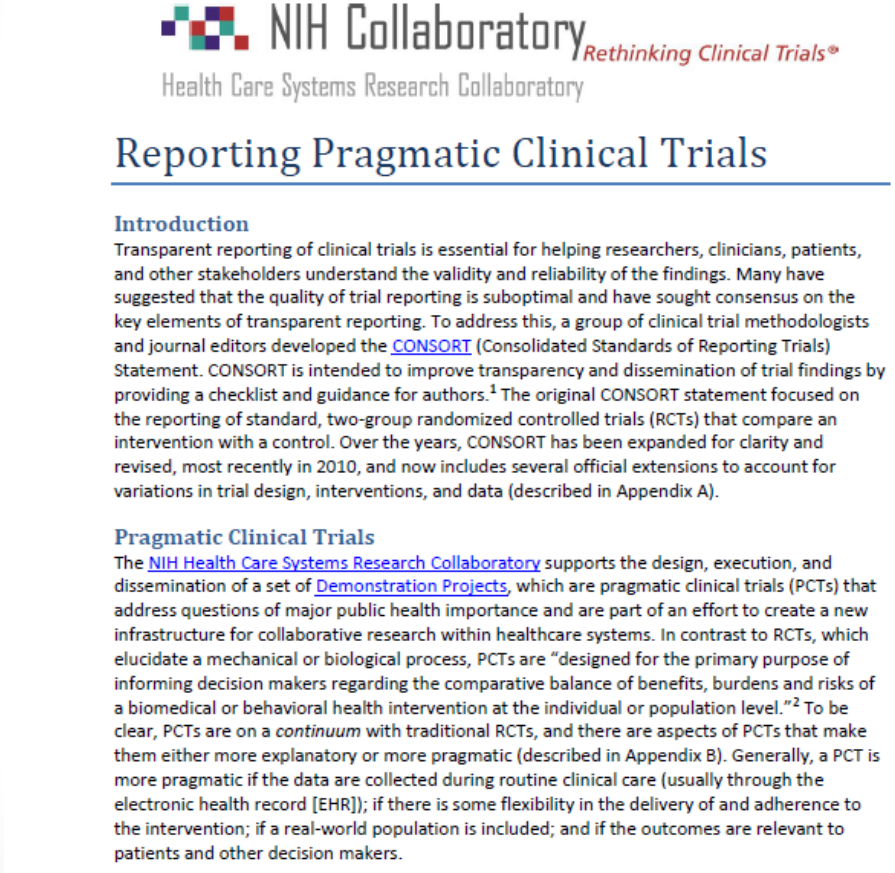
Special considerations for ePCTs

- Who were the stakeholders & how were they engaged to participate in the design, conduct, or dissemination?
- Was cluster randomization used?
- How were data from EHRs used in the research?
- How were unanticipated changes in study arms accommodated?
- Did the trial need alternate approaches to informed consent or protection of human subjects?

PCT Reporting Template



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Reporting Pragmatic Clinical Trials

Introduction

Transparent reporting of clinical trials is essential for helping researchers, clinicians, patients, and other stakeholders understand the validity and reliability of the findings. Many have suggested that the quality of trial reporting is suboptimal and have sought consensus on the key elements of transparent reporting. To address this, a group of clinical trial methodologists and journal editors developed the CONSORT (Consolidated Standards of Reporting Trials) Statement. CONSORT is intended to improve transparency and dissemination of trial findings by providing a checklist and guidance for authors.[1] The original CONSORT statement focused on the reporting of standard, two-group randomized controlled trials (RCTs) that compare an intervention with a control. Over the years, CONSORT has been expanded for clarity and revised, most recently in 2010, and now includes several official extensions to account for variations in trial design, interventions, and data (described in Appendix A).

Pragmatic Clinical Trials

The NIH Health Care Systems Research Collaboratory supports the design, execution, and dissemination of a set of Demonstration Projects, which are pragmatic clinical trials (PCTs) that address questions of major public health importance and are part of an effort to create a new infrastructure for collaborative research within healthcare systems. In contrast to RCTs, which elucidate a mechanical or biological process, PCTs are "designed for the primary purpose of informing decision makers regarding the comparative balance of benefits, burdens and risks of a biomedical or behavioral health intervention at the individual or population level."[2] To be clear, PCTs are on a *continuum* with traditional RCTs, and there are aspects of PCTs that make them either more explanatory or more pragmatic (described in Appendix B). Generally, a PCT is more pragmatic if the data are collected during routine clinical care (usually through the electronic health record [EHR]); if there is some flexibility in the delivery of and adherence to the intervention; if a real-world population is included; and if the outcomes are relevant to patients and other decision makers.

Find a copy of the PCT Reporting Template in your meeting materials

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PCT Reporting Template

Follows CONSORT headings with additional considerations for embedded PCTs:

- How data from EHR were collected & validated
- How changes in study arms were accommodated
- How and when stakeholders were engaged
- How and when informed consent was obtained

Living Textbook: Reporting and Dissemination

- Chapters reflect first-hand experiences from the Demonstration Project Principal Investigators
- Case studies illustrate challenges and real-world solutions to the implementation & dissemination of ePCTs

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Data sharing and reporting

From the *Living Textbook* chapter on data sharing and embedded research

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Key takeaways

- Embedded pragmatic trials bring tradeoffs in flexibility, adherence, and generalizability
- Endpoints and outcomes should be meaningful to providers and patients
- Real-world evidence from ePCTs can promote sustainable ways to improve healthcare