

Reporting ePCT Results

Adrian Hernandez, MD, MHS
Duke University School of Medicine
Duke Clinical Research Institute

Goal of transparent reporting

“Good reporting allows decision makers to judge how applicable the results of the PCT are to their own conditions and environments.”

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

The screenshot shows the ClinicalTrials.gov website. At the top left is the NIH logo and the text "U.S. National Library of Medicine". Below this is the "ClinicalTrials.gov" logo. To the right are navigation links: "Find Studies", "About Studies", "Submit Studies", "Resources", and "About S". A blue banner contains the text: "ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world." Below the banner, on the left, is a section titled "Explore 271,886 research studies in all 50 states and in 203 countries." followed by a paragraph about the site's purpose, an "IMPORTANT" disclaimer, and a note about participating in a study. On the right is a "Find a study" search form with the following fields: "Recruitment status" (radio buttons for "Recruiting and not yet recruiting studies" and "All studies"), "Condition or disease" (text input), "Other terms" (text input), and "Country" (dropdown menu). There are "X" icons to clear each input field. At the bottom of the form are "Search" and "Advanced Search" buttons.

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

CONSORT TRANSPARENT REPORTING OF TRIALS

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Explore Extensions

Pragmatic Trials

[Explore Checklist](#)

The CONSORT extension for pragmatic trials builds upon the existing CONSORT relation to pragmatic trials. For each of the eight items the standard CONSORT item, and an explanation of the issues are presented. Importantly, these suggest CONSORT explanatory paper and where relevant, other CONSORT guidance.

Pragmatic trials are designed to measure effectiveness; that is whether an intervention is applicable (also called generalisability) in a wide range of usual care settings of participants to whom the intervention will be applied in the real world, or recipients of health care to use evidence from trials in policy decisions has in their usefulness.

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Patient-Reported Outcomes (CONSORT PRO)

[Explore Checklist](#)

The 2013 CONSORT-PRO extension provides guidance for authors of trials describing patient-reported outcomes. Specifically, it updates the CONSORT 2010 checklist to facilitate optimal reporting of RCTs in which PROs are primary or secondary end points.

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Pilot and Feasibility Trials

The CONSORT extension for randomised pilot and feasibility trials is meant to provide guidance for reporting on a future definitive RCT, or part of it, is conducted on a smaller scale, regardless of whether the pilot is conducted before, during, or after the main trial. The extension covers the design of a main trial, non-randomised pilot and feasibility studies, or phase randomised pilot and feasibility studies and so many of the principles might be different.

There are some key differences in pilot and feasibility studies from standard randomised controlled trials. Some items need to be reported and in the interpretation of standard CONSORT reporting, some items need to be retained, but most have been adapted, some removed, and new items added.

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Cluster Trials

[Explore Checklist](#)

The CONSORT extension for Cluster Trials was updated in 2012 to be consistent with the main CONSORT Statement. The main CONSORT Statement provides recommendations for reporting on randomised controlled trials. Cluster trials, however, are randomised to health care interventions rather than to individual patients. The main issue associated with their randomised trials, is that two different units of measurement—the cluster and the individual patient—must be reported.

CONSORT pragmatic trial extension

“The usefulness of a trial report ... depends on the clarity with which it details the relevance of its interventions, participants, outcomes, and design to the clinical, health service, or policy question it examines.”

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

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



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*



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

The screenshot displays the NIH Collaboratory Living Textbook website. The header includes the title 'NIH COLLABORATORY LIVING TEXTBOOK of Pragmatic Clinical Trials' and navigation links for HOME, WELCOME, GRAND ROUNDS, and NEWS. Below the header are three main sections: DESIGN, CONDUCT, and DISSEMINATION. The DISSEMINATION section is highlighted in a dark green box. The main content area shows the title 'DISSEMINATION APPROACHES FOR DIFFERENT STAKEHOLDERS' and 'SECTION 3 Reporting to the Scientific Community: ClinicalTrials.gov'. A list of contributors is provided, including Leah Tuzzio, David Chambers, Ellen Tambor, Jerry Sals, Beverly B. Green, Susan Huang, Kevin W., and Doug Z. A sidebar on the right lists sections: 1 Introduction, 2 Reporting to the Scientific Community: General Considerations, 3 Reporting to the Scientific Community: ClinicalTrials.gov, 4 Dissemination to Patients, 5 Dissemination to Health System Leaders, and 6 Additional Resources. A large dark green box at the bottom of the screenshot features the word 'DISSEMINATION' and a list of topics: Data Sharing and Embedded Research, Dissemination and Implementation, and Dissemination Approaches for Different Stakeholders.

Data sharing and reporting

“Emerging policies and procedures for sharing analyzable research datasets hold great promise for increasing transparency and reproducibility in medical research.”

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

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