SPIRIT

Standard Protocol Items: Recommendations for Interventional Trials

THE SPIRIT INITIATIVE:
DEFINING STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS
Executive summary (August 2011)

Project outline

The protocol for a clinical trial serves as the foundation for study conduct and reporting. With recent international policies and legislation mandating public access to information from protocols, these documents have become increasingly important for transparency and evaluation of trial results. Full knowledge of a trial protocol allows an appropriate ethical assessment before trial inception, and the proper critical appraisal of the results after trial completion.

However, the quality of protocols varies greatly, partly due to variable standards and guidelines. Previous studies have demonstrated that a high percentage of trial protocols do not address important issues such as primary outcomes, data analysis, competing interests, and publication restrictions.

The SPIRIT initiative (Standard Protocol Items: Recommendations for Interventional Trials) has finalized an evidence-based checklist that defines the key items to be addressed in trial protocols, leading to improved quality of protocols and enabling accurate interpretation of trial results. The project has been co-funded by the Canadian Institutes of Health Research, National Cancer Institute of Canada, and Canadian Agency for Drugs and Technologies in Health. The SPIRIT group includes experts from key stakeholder groups.

The SPIRIT methodology includes two systematic reviews of existing protocol guidelines and empiric evidence; a Delphi consensus process with three survey rounds conducted in 2007 (96 participants from 17 countries); and two consensus meetings (19 participants) held in 2007 and 2009. The final product consists of a 33-item checklist (completed) and an explanatory paper (under development) providing the rationale and evidence base for each recommended item.

The SPIRIT initiative has distinct strengths:

- Evidence-based approach with up-to-date, systematically-identified references to empiric studies;
- Broad international representation, consultation, and endorsement across key stakeholder groups;
- Transparent methodology based on the latest recommendations for developing reporting guidelines;
- Planned pilot-testing coupled with integration of an evaluative component to assess future impact.

SPIRIT Checklist – Section headings

1. Administrative information
2. Introduction
3. Methods: Participants, interventions, outcomes
4. Methods: Assignment of interventions (for controlled trials)
5. Methods: Data collection, management, analysis
6. Methods: Monitoring
7. Ethics and dissemination
8. Appendices

Impact

The evidence-based SPIRIT recommendations will benefit researchers, trial participants, patients, sponsors, funders, research ethics committees, peer reviewers, trial registries, journals, policymakers, regulators and other key stakeholders by providing standards for the core information in trial protocols and improving their quality; facilitating registration and critical appraisal of trials; and ultimately enhancing transparency in clinical trials research.

Funders:

CIHR IRSC Canadian Institutes of Health Research / Instituts de recherche en santé du Canada

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National Cancer Institute of Canada / Institut national du cancer du Canada

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