



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## SPIRIT-C and CONSORT-C

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Irmgard Eichler

An agency of the European Union





# SPIRIT-C

[SPIRIT \(Standard Protocol Items for Randomized Trials\)](#) published in 2013,

- Evidence-based guidance to define key items to be addressed in trial protocols
- Aim: - to improve quality of protocols  
- to enable accurate interpretation of trial results.
- Endorsed by high-ranking peer-reviewed journals, research institutions, the Cochrane Consumer Network and some pharma companies. Recently, the UK and Swiss national ethics committees took up the SPIRIT recommendations.
- Trials in children require additional and modified standards to cover the complexity associated with trials in the paediatric population.
- **SPIRIT-C** will be an extension of the SPIRIT 2013 statement, providing a checklist and guidance for the design and conduct of clinical trials in the paediatric population.
- <http://www.sickkids.ca/Research/EnRICH/Research-Projects-and-Initiatives/SPIRIT-C/index.html>



# CONSORT-C

## CONSORT (Consolidated Standards of Reporting Trials)

- standard way for authors to prepare reports of trial findings,
- facilitating complete and transparent reporting
- aiding critical appraisal and interpretation

**BUT** specific elements for trials with children, from newborn babies to adolescents, detailing intervention, drug dose, delivery, validity of outcomes studied not included

**CONSORT-C** will extend the current CONSORT statement

- highlighting key elements in the reporting of pediatric trials that differ from adult trials
- will develop a checklist of essential items that authors should include when reporting the main results of paediatric clinical trials
- with the aim to improve quality of information reported from paediatric trial
- <http://www.sickkids.ca/Research/EnRICH/Research-Projects-and-Initiatives/CONSORT-C/index.html>



## SPIRIT-C and CONSORT-C

- Delphi process to generate possible reporting standards for the guideline in 2014
- Consensus meeting in Sept 2014 to finalise SPIRIT-C and CONSORT-C to
  - achieve consensus on final key items in protocol development, trial design and conduct, as well as trial reporting
  - plan a knowledge translation strategy to disseminate the SPIRIT-C and CONSORT-C guidelines and to ensure endorsement