EPTRI General Assembly and Scientific Meeting
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SPIRIT-C AND CONSORT-C GUIDELINES

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My financial disclosure statement is in the public domain.

Nothing relevant to the current presentation

SPIRIT = Standard Protocol Items: Recommendations for Interventional Trials

Purpose: Ensure that ***planned*** clinical trials are scientifically robust, ethical, and fully transparent.

- **Prevents bias at the design stage** Forces upfront declaration of objectives, outcomes, randomization, blinding, and analysis plans.
- **Enables reproducibility** Provides enough methodological detail for others to replicate or audit the trial.
- **Supports ethical review & regulatory assessment** Clear intervention description, safety monitoring, and feasibility evaluation.
- **Reduces selective reporting** Locks in outcomes and analyses before the trial begins.
- **Improves trial credibility** Funders, regulators, and ethics committees rely on SPIRIT to judge scientific merit.

Core Insight: SPIRIT is an *anti-distortion framework* — it limits analytic flexibility and protects participants by ensuring the trial is worth running.

CONSORT = Consolidated Standards of Reporting Trials

Purpose: Ensure that ***completed*** trials are reported transparently, completely, and in a way that allows critical appraisal.

- **Prevents biased or incomplete reporting** Requires disclosure of deviations, attrition, harms, and all prespecified outcomes.
- **Enables interpretation and comparison** Standardized structure (flow diagram, baseline table, effect estimates, precision).
- **Supports systematic reviews & meta-analyses** Clear reporting of methods and results reduces heterogeneity and misclassification.
- **Strengthens clinical decision-making** Transparent reporting prevents misleading conclusions that could harm patients.
- **Improves accountability** Journals and regulators use CONSORT to ensure trials meet scientific standards.

Core Insight: CONSORT is the *public transparency layer* — it prevents distortion of evidence after the trial is completed.

ELSEVIER

Journal of Clinical Epidemiology ■ (2023) ■

Journal of Clinical Epidemiology

ORIGINAL ARTICLE

Reporting standards for child health research were few and poorly implemented

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Abstract

Objectives: This study aims to identify existing reporting standards for child health research, assess the robustness of the standards development process, and evaluate the dissemination of these standards.

"There is a quantitative and qualitative paucity of well-developed reporting standards for child health research."

Li Q, et al.
J Clin Epidemiol. 2023

Why SPIRIT-C adds value

Child-specific ethical safeguards Clear justification of risk–benefit in minors; explicit assent/consent pathways; age-appropriate burden minimization.

Developmental considerations Requires detailing how growth, maturation, and developmental pharmacology influence dosing, endpoints, and monitoring.

Pediatric feasibility & acceptability Mandates upfront planning for school schedules, caregiver involvement, hospitalizations, and long-term follow-up logistics.

Enhanced safety planning More granular adverse event monitoring, including developmental toxicities, neurocognitive outcomes, and growth trajectories.

Appropriate endpoint selection Forces justification of surrogate endpoints, composite outcomes, and functional measures relevant to children.

Equity & vulnerability safeguards Addresses inclusion of rare-disease populations, small-N cohorts, and children with limited decision autonomy.

Why CONSORT-C adds value

Transparent reporting of age-stratified outcomes Requires disaggregation by age, developmental stage, weight bands, and pubertal status — critical for ATMPs.

Detailed harms reporting for children Mandates explicit reporting of growth effects, neurodevelopmental outcomes, school functioning, caregiver burden, and long-term sequelae.

Clear description of pediatric recruitment & retention Addresses challenges such as parental consent, assent withdrawal, and attrition due to burden or disease progression.

Intervention fidelity in pediatric settings Requires reporting of adherence, caregiver-administered components, and modifications needed for younger participants.

Contextualization of results for clinical practice Encourages reporting on feasibility in real-world pediatric care pathways, including multidisciplinary support.

Improved interpretability for regulators & HTA bodies Provides structured information needed for pediatric benefit–risk assessment, extrapolation, and modelling.

Weighted insight

SPIRIT-C reduces protocol ambiguity in pediatric ATMP trials, where small sample sizes, long-term risks, and developmental variability make generic SPIRIT insufficient.

Weighted insight

CONSORT-C prevents misinterpretation of pediatric trial results by forcing disclosure of developmental, safety, and feasibility factors that generic CONSORT does not capture.

The Lancet Group
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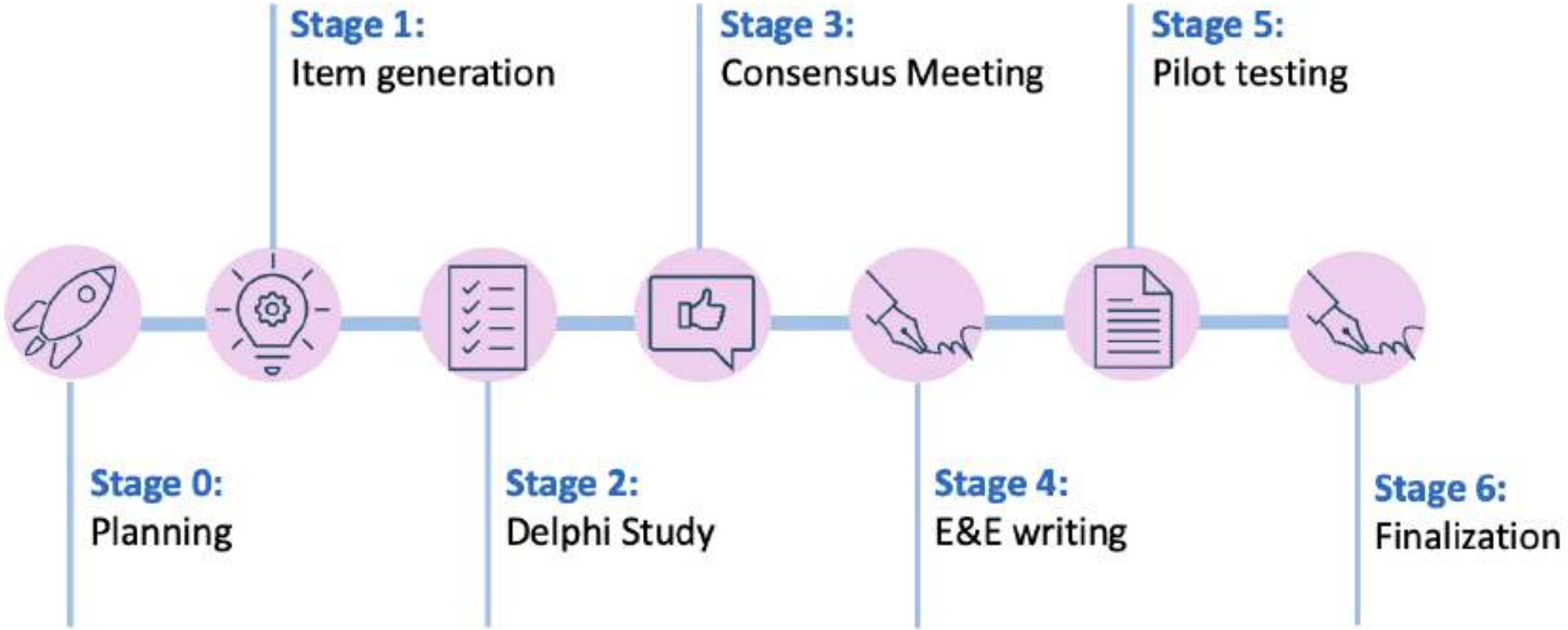
"A new era for child and adolescent health research"

Uncertainty remains in the evidence base for child and adolescent health. Trial quality is inconsistent, numbers lag behind adults, and young people's needs are often inadequately considered.

Just published in The Lancet Child & Adolescent Health, the CONSORT-C and SPIRIT-C guideline extensions mark a new era for the field. Implemented widely, these guidelines "will have a profound impact on child and adolescent health and equity", say editors.

Adopt CONSORT-C and SPIRIT-C in your work and read the accompanying Editorial ⬇️
CONSORT-C statement: http://spkl.io/6040AvfH6
SPIRIT-C statement: http://spkl.io/6041AvfHB
Editorial: http://spkl.io/6042AvfH8


Stage 1:
Item generation
Stage 3:
Consensus Meeting
Stage 5:
Pilot testing
Stage 0:
Planning
Stage 2:
Delphi Study
Stage 4:
E&E writing
Stage 6:
Finalization

What Young People and Parents Need to Know When Reading Clinical Trial Reports

Well-reported clinical trials are essential to patients' evidence-informed health care decisions.

In recent years, there have been more efforts to improve the communication of clinical trial results back to participants and their families. While there are many ways to communicate trial results, one of the most common ways trial teams share their findings with the world is through a clinical trial report. These are often published in journals like *JAMA Pediatrics*. Clinical trial reports are important because they describe what was done, what was found, and what the results mean.

As a young person or parent, clinical trial reports may help you make health care decisions. Maybe you have read a report for a clinical trial that you or your child participated in, or you want to learn more about health conditions or available treatments. While reading, you may find it difficult to find answers to the questions you have. This happens a lot, as clinical trial reports often miss or leave out key details from the trial, often to save space. At times, there may not be enough information on trial interventions and outcomes measured in children of different ages.

To help with this, new guidance to improve reporting in child health and pediatric clinical trial reports is now available. These are writing tools that help authors clearly report key trial details in protocols and trial reports. They are called *Standard Protocol Items: Recommendations for Interventional Trials–Children and Adolescents* (SPIRIT-C) and *Consolidated Standards of Reporting Trials-Children and Adolescents* (CONSORT-C).

Importantly, SPIRIT-C and CONSORT-C were developed with the help of young people and parents who have some experience with child health trials.

SPIRIT-C and CONSORT-C include topics that young people and parents think should be reported in a trial protocol and report. For example, young people often want to know if the trial interventions need a support person's help. They also want to know how confidentiality is respected in the trial. Other key details might include why the trial needs to be done with children and how potential harms were reduced. Young people also want details on whether or how participants will be recognized for their time and efforts.

ers know what information to expect. Readers can then critically consider the information and how it was reported. They can also better judge whether the trial results are relevant to them. Knowing this will empower children, young people, and their families to make the right health care decisions for them.

FOR MORE INFORMATION

Enhancing the Quality and Transparency of Health Research (EQUATOR) Network
https://www.equator-network.org/toolkits/using-guidelines-in-

JAMA Pediatrics
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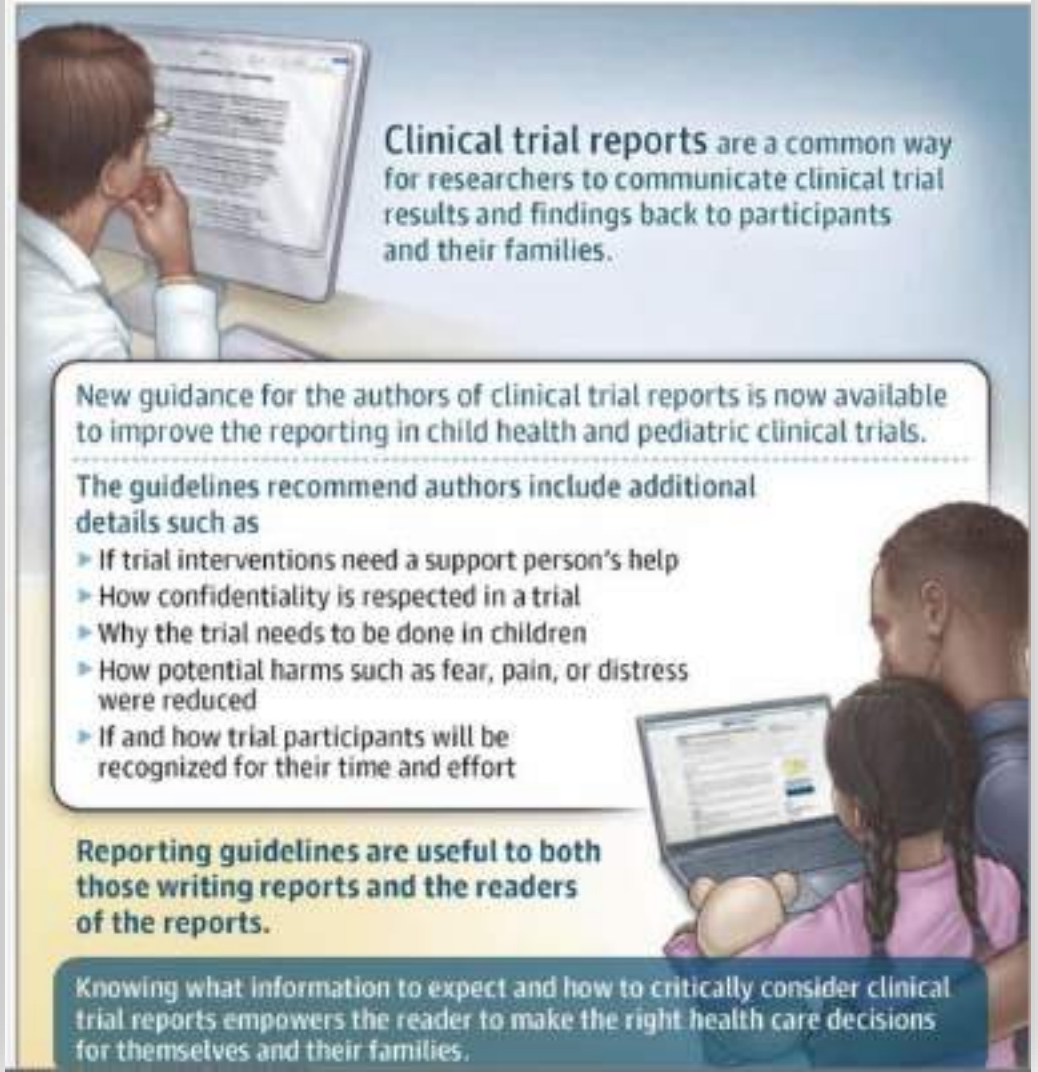
This JAMA Pediatrics Patient Page describes how new guidance aiming to improve reporting of clinical trials may help young people and parents find information to make the right health care decisions for them.

https://ja.ma/472KHyS



Reporting of paediatric randomised controlled trials aimed at improving health outcomes in children and adolescents aged 0-19 years

- **SPIRIT-Children and Adolescents (SPIRIT-C) 2026**
  - 17 new reporting items for paediatric trial protocols (4 youth generated items and 6 youth endorsed items)

- **CONSORT-Children and Adolescents (CONSORT-C) 2026**
  - 13 new reporting items for paediatric trial reports (1 youth generated item and 6 youth endorsed items)

SPIRIT | CONSORT
CHILDREN & ADOLESCENTS
Reporting Guidelines for Child Health Trials

SPIRIT | CONSORT CHILDREN & ADOLESCENTS

SPIRIT-C 2026

Item 16.1: Outcomes

Explanation of the validity, reliability, feasibility, and responsiveness of the outcome measurement instruments for the prespecified age groups

Administrative information	1a.1	Title and structured summary
Open science	6.1	Data sharing
Introduction	9a.1	Background and rationale *Prevalence/incidence*
	9a.2	Background and rationale *Extrapolation*
	9a.3	Background and rationale *Research question or aim*
Methods	13.1	Trial setting
	14a.1	Eligibility criteria
	15a.1	Intervention and comparator *Dose/formulation*
	15a.2	Intervention and comparator *Adaptations*
	15a.3	Intervention and comparator *Intervention delivery*
	16.1	Outcomes
	17.1	Harms *Mitigation measures*
	17.2	Harms *Efforts to reduce risk*
	20.1	Recruitment *Impact of trial participation*
	20.2	Recruitment *Recognition for trial participation*
Ethics	32a.1	Consent or assent
	34.1	Ancillary and post-trial care

Key elements for reporting this item:

- Justification and relevance of the outcome measurement instrument(s) for the prespecified age/developmental group(s) and where relevant, the specific health condition
- Validity, reliability, responsiveness, and feasibility of trial outcome measurement instruments in the target population
- Who is assessing/reporting the outcomes or gathering the outcome data using the trial outcome measurement instrument, and whether the outcome measurement instrument(s) are child/adolescent centred (eg, if parent reported outcome, clearly specify whether the measure is a parent proxy report of child outcomes, or a parent self-report).

Examples:

"Functional independence level: The WeeFIM (functional independence measure) instrument is a useful pediatric functional independence assessment tool for children aged 6 months to 7 years and for children with developmental disabilities aged 6 months to 21 years . . . The WeeFIM is a psychometrically sound instrument in terms of its reliability, validity, and responsiveness[reference]. . . . Quality of life: The Short Form 36 (SF-36) is used to evaluate parents' quality of life; it is a widely used health status survey designed to assess quality of life by measuring the individual's self-perception of his/her own health status with 8 multi-item scales, including physical functioning, physical role functioning, bodily pain, general health, vitality, social functioning, emotional role functioning, and mental health, and one single item of health transition. It can be used to assess the quality of life for patients with various diseases or people in general. The reliability, validity, and sensitivity of the Chinese (simple) SF-36v2 have been verified[reference]."

Du Q, Baden Y, Liu HH, et al. A home-based exercise program for children with congenital heart disease following interventional cardiac catheterization: study protocol for a randomized controlled trial. Trials 2017;18:38. doi:10.1186/s13063-016-1773-7

See the E&E for more examples.

Statement (co-published in *The BMJ, JAMA Pediatrics, and The Lancet Child and Adolescent Health*): Baba A, Smith M, Potter BK, et al. SPIRIT-Children and Adolescents (SPIRIT-C) 2026 Extension Statement: Enhancing the Reporting and Usefulness of Paediatric Randomised Trial Protocols. BMJ 2026;392:e085963. doi: 10.1136/bmj-2025-085963

Explanation and Elaboration: Baba A, Smith M, Potter BK, et al. SPIRIT-C 2026 explanation and elaboration: recommendations for enhancing the reporting and impact of paediatric randomised trials. BMJ 2026;392:e085964. doi: 10.1136/bmj-2025-085964

More resources are available at https://bit.ly/spirit-children-adolescents-resources

SPIRIT | CONSORT CHILDREN & ADOLESCENTS

CONSORT-C 2026

Item 14.1: Outcomes

Explain evidence supporting validity of selected outcomes and outcome measurement instruments in age group(s) included

Title and abstract	1a.1	Title and structured abstract
Introduction	6.1	Background and rationale *Prevalence/incidence*
	6.2	Background and rationale *Efficacy/effectiveness*
	6.3	Background and rationale *Research question or aim*
Methods	12a.1	Eligibility criteria *Justification for including multiple age groups*
	12a.2	Eligibility criteria *Age-appropriate trial information*
	13.1	Intervention and comparator *Dose/formulation*
	13.2	Intervention and comparator *Intervention delivery*
	14.1	Outcomes
	15.1	Harms
Results	25.1	Baseline data
	28.1	Ancillary analyses
Discussion	29.1	Interpretation

Key elements for reporting this item:

- Justification of the relevance and importance of trial outcomes to the participating age/developmental group(s)
- Validity of the outcome measurement instrument for the prespecified age group(s)
- Any (known) variability in validity of outcome measures across age ranges/age subgroups of trial participants; rationale for the selection of different outcome measures for each age subgroup
- Describe who assesses the outcomes and whether the outcome measurement instrument(s) are child/adolescent centred (eg, if parent reported outcome, clearly specify if the measure is a parent proxy report of child outcomes, or a parent self-report).

Examples:

"Each patient also completed an age-appropriate [visual analog scale] VAS to determine their level of pain and anxiety before the procedure. Each VAS was scored on a scale from 0 to 10, with 10 indicating the worst pain or anxiety. Based on precedent and prior validation studies on VAS in children and adolescents[reference], patients aged 4 to 7 years used a VAS that included both Wong-Baker FACES and a numerical rating scale, while patients aged 8 to 14 years were presented with a numerical rating scale only. When the provider was ready to begin the procedure, the video or game was initiated. The patient's heart rate was continuously monitored throughout the procedure, and the highest and lowest heart rate were recorded to calculate change. After the procedure, patients completed the pain and anxiety VAS again. Heart rate has been used as a valid means to objectively quantify the physiologic response to pain and anxiety in children[reference]. Furthermore, VAS measures are commonly used in children and adults to quantify subjective experiences of pain and anxiety[reference]."

Fabrizio PD, Gray PW, Mackie AT, et al. Virtual Reality Distraction Is No Better Than Simple Distraction Technique for Reducing Pain and Anxiety During Pediatric Orthopaedic Outpatient Procedures: A Randomized Controlled Trial. Clin Orthop Relat Res. 2024;482:884-93. doi:10.1097/CORR.0000000000002888

See the E&E for more examples.

Statement (co-published in *The BMJ, JAMA Pediatrics, and The Lancet Child and Adolescent Health*): Baba A, Smith M, Potter BK, et al. CONSORT-Children and Adolescents (CONSORT-C) 2026 Extension Statement: Enhancing the Reporting and Impact of Paediatric Randomised Trials. BMJ 2026;392:e085961. doi: 10.1136/bmj-2025-085961

Explanation and Elaboration: Baba A, Smith M, Potter BK, et al. CONSORT-C 2026 explanation and elaboration: recommendations for enhancing the reporting and impact of paediatric randomised trials. BMJ 2026;392:e085963. doi: 10.1136/bmj-2025-085963

More resources are available at https://bit.ly/spirit-children-adolescents-resources

SPIRIT 2025	SPIRIT-C 2026 extension:
#9a: Scientific background and rationale, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	9a.1*† Describe the prevalence/incidence of the disease or condition in children/adolescents 9a.2† Describe the potential for extrapolation from other paediatric populations or adult data, or why extrapolation is not considered appropriate 9a.3* Include a description of the research question or aim with a justification for undertaking the trial in children/adolescents

SPIRIT-C #9a.1-2-3 Background and rationale

SPIRIT 2025	SPIRIT-C 2026 extension:
#15a Intervention and comparator with sufficient details to allow replication including how, when, and by whom they will be administered. If relevant, where additional materials describing the intervention and comparator (e.g., intervention manual) can be accessed	15a.1*† Describe whether there is an intervention dose and/or formulation appropriate for the trial population, and if there are any adjustments made based on age, weight, or body surface area 15a.2† Give rationale for adapting interventions used in other paediatric populations or adults for the present trial 15a.3*† Describe whether the trial interventions will be delivered with help from a support person

SPIRIT-C 15a.1-2-3: Intervention and comparator

SPIRIT 2025	SPIRIT-C 2026 extension:
#17 How harms are defined and will be assessed (e.g., systematically, non-systematically)	17.1*† Describe whether trial interventions and/or procedures will induce fear, pain, distress, or are invasive, and what measures are taken to mitigate this 17.2 Describe all efforts to reduce the child/adolescent's risk associated with trial participation

SPIRIT-C #17.1-2: Harms

CONSORT-C 12a.1: Methods – Eligibility criteria

CONSORT 2025:	CONSORT-C 2026 extension:
#12a: Eligibility criteria for participants	#12a.1: Provide a justification for including multiple age groups of children/adolescents at different developmental stages, and address potential age or development-related differences in treatment effects

CONSORT-C 13.1:
Methods - Intervention and comparator

CONSORT 2025:	CONSORT-C 2026 extension:
#13: Intervention and comparator with sufficient details to allow replication. If relevant, where additional materials describing the intervention and comparator (eg, intervention manual) can be accessed	#13.1: Describe whether there is an intervention dose and/or formulation appropriate for the trial population, and if there were any adjustments made based on age, weight, or body surface area

Table 2 | Implementable actions of key user groups, and resulting benefits from use of SPIRIT-C (SPIRIT-Children and Adolescents) 2026

Key groups	Implementable actions	Potential benefits
Trial protocol authors	• Adhere to the SPIRIT-C 2026 checklist and refer to the corresponding explanation and elaboration paper when writing trial protocols • Cross use with other existing SPIRIT extensions, depending on condition, design, intervention, and outcomes	• Improved reporting of standardised minimum set of key elements, resulting in comprehensive, transparent, and useful trial protocols: improved appraisal, better implementation, and fewer amendments • Inclusion of details that were identified as important by young people and family caregivers • Better understanding of the minimum set of reporting items that needs to be included in trial protocols involving children and adolescents • Downstream effects on trial conduct, analysis and reporting • Improved detection of selective (trial outcome) reporting • Improved ability to synthesise results to generate recommendations for clinical guidelines
Trial/research staff	• Use SPIRIT-C 2026 as a training tool to increase awareness of and understanding of conduct, analysis, and reporting of paediatric trials	• Improved understanding of trial concepts • Reduce risk of bias that may result from trial conduct • Improved adherence to the trial protocol and better implementation of the trial
Trainees (eg, graduate and medical students, residents, research fellows, clinical fellows)	• Use SPIRIT-C 2026 as a training tool to increase awareness of and understanding of design, planning, and reporting of paediatric trials	• Increased familiarity with the minimum set of reporting items to be reported in paediatric trial protocols • Improved understanding and awareness by future generations in responsible research practice including the use of research reporting guidelines, fostering comprehensive and useful study protocols
Patients, public, trial participants	• Familiarise self with SPIRIT-C 2026 to know what information to expect when reading a trial protocol or participating in a paediatric trial • Empower family caregivers to fully understand what the trial entails and support their child • Advocate for the use of reporting guidelines, such as SPIRIT-C 2026, by authors, journals, funders, and institutions	• Improved understanding of content that should be reported in trial protocols that facilitate the generation of high quality knowledge that helps inform healthcare decision making • Increased awareness and empowerment of the general public in holding investigators and the research enterprise accountable for proper research conduct, reporting, and appropriate spending of funding • Increased trust and accountability in research

EPTRI Webinar Series

CONSORT- and SPIRIT-Children: Reflections on Emerging Guidelines for Paediatric clinical Trials

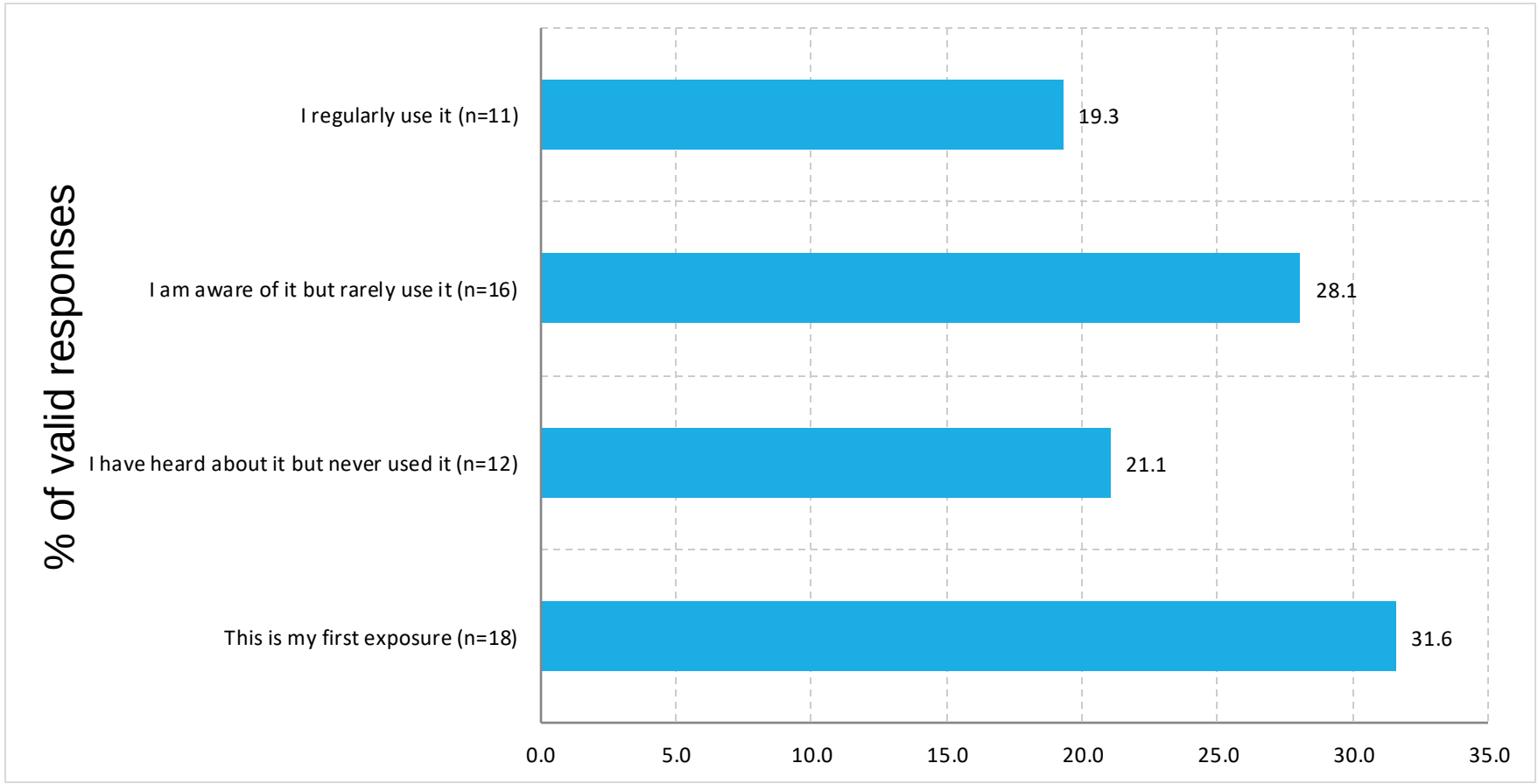
EUROPEAN PAEDIATRIC TRANSNATIONAL RESEARCH INFRASTRUCTURE

Eptri's contribution

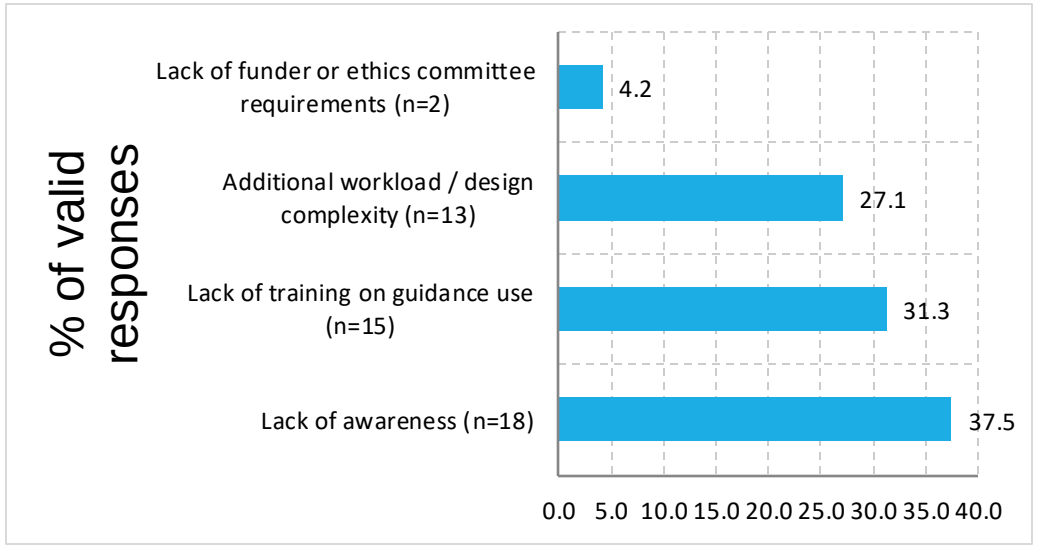
Key advantages from a methodological point of view:

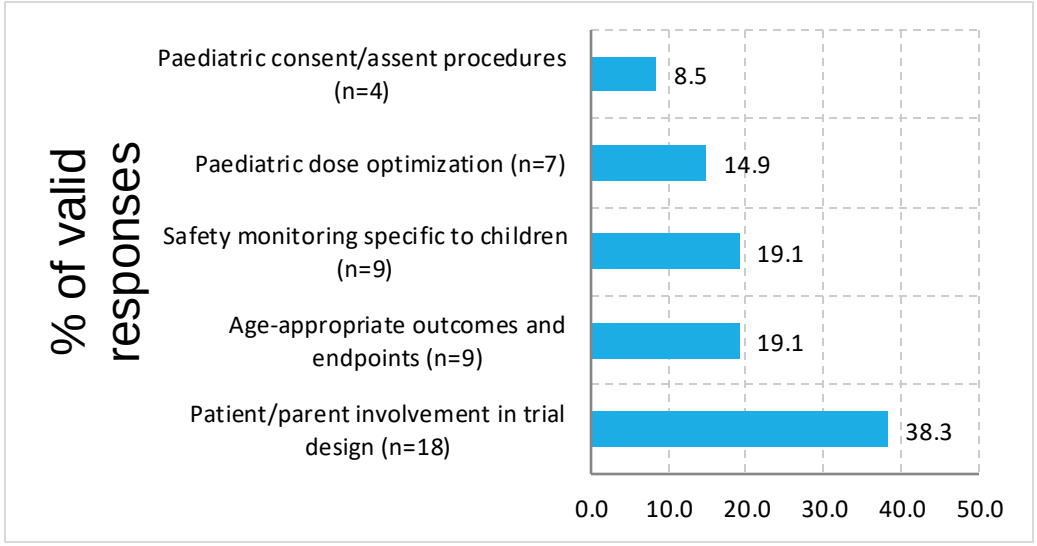
1. Improved transparency
   - accelerating translation of effective interventions into clinical practice
2. Improved reproducibility
   - better study replication
3. Improved usability
   - facilitates applicability of trial results for decision-making and pediatric policy

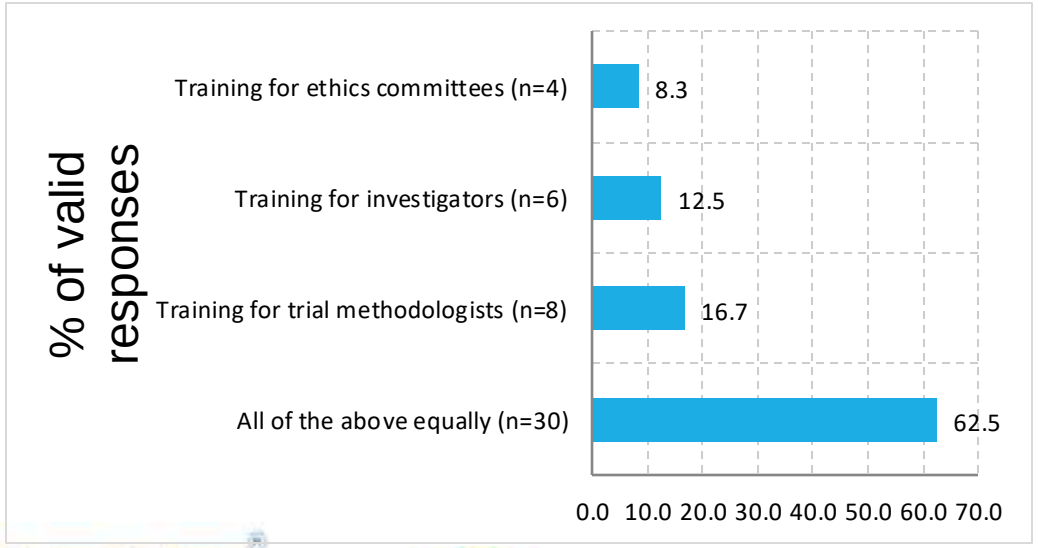
awareness on the guidelines

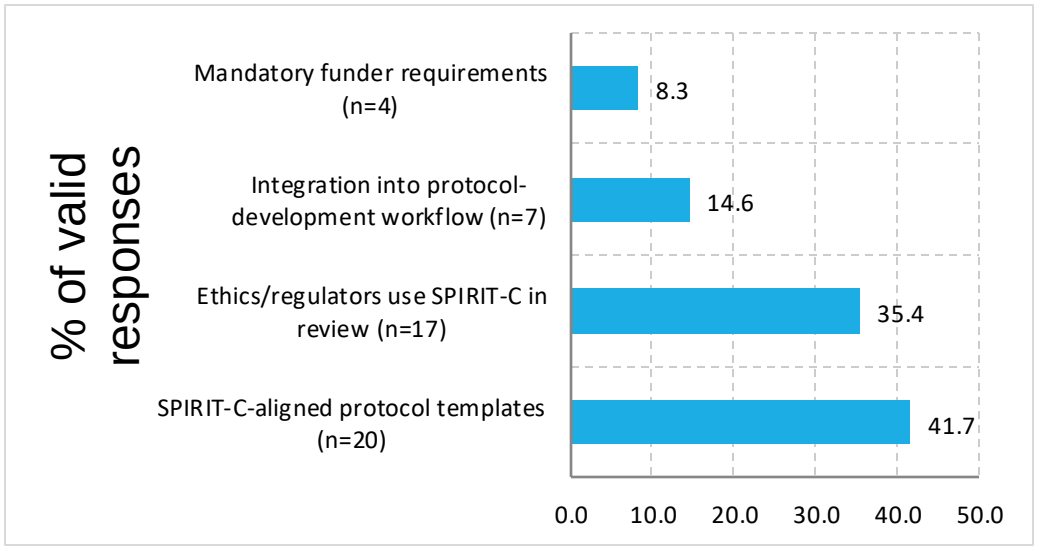


barriers, shortages, training needs, improvements (SPIRIT)









burdens, training, implementation (CONSORT)