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

SPIRIT-C 2026

Item 9a.3: Background and rationale – Research question or aim

Include a description of the research question or aim with a justification for undertaking the trial in children/adolescents

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:

- Need for the trial in the context of existing paediatric evidence
- Rationale for including specific age range(s)
- Whether the trial will be done for regulatory purposes.

Examples:

"(Abstract-Background) "This trial is part of the European Union Seventh Framework Programme project Gabapentin in Paediatric Pain (GAPP) to develop a pediatric use marketing authorization for a new gabapentin suspension . . . (Background) In this context, the GAPP (Gabapentin in Paediatric Pain) project is a European-funded project that comprises a full pediatric development program for gabapentin in the treatment of chronic neuropathic or mixed pain in children. The development strategy, requirements, and regulatory deliverables have been outlined in a pediatric investigation plan (PIP), which has agreed with and approved by the European Medicines Agency's Paediatric Committee. The PIP includes (1) the development of a liquid oral gabapentin formulation, (2) the evaluation of gabapentin safety in juvenile animal toxicity studies (PRE-GABA), (3) two clinical trials to evaluate the efficacy and safety of gabapentin as monotherapy (GABA-1) and as adjuvant therapy (GABA-2), and (4) a modeling bridging study (GABA-3) to specifically address the paucity of pharmacokinetic (PK) data in children and enhance the dose rationale for the pediatric population[reference]. The study protocol presented in this paper concerns the GABA-2 trial. The primary aim of this specific study (GABA-2) is to determine the efficacy and safety of gabapentin versus placebo as add-on to morphine in children with severe chronic neuropathic or mixed pain."

de Leeuw TG, Mangiarini L, Lundin R, et al; GAPP consortium. Gabapentin as add-on to morphine for severe neuropathic or mixed pain in children from age 3 months to 18 years - evaluation of the safety, pharmacokinetics, and efficacy of a new gabapentin liquid formulation: study protocol for a randomized controlled trial. Trials 2019;20:49. doi:10.1186/s13063-018-3169-3.

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:e085062. doi: 10.1136/bmj-2025-085062

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:e085064. doi: 10.1136/bmj-2025-085064