Enhancing reporting and usefulness of paediatric randomised trial protocols: SPIRIT-Children and Adolescents (SPIRIT-C) 2026 extension

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APPENDICES

eAppendix 1. Protocol amendments and added procedures in the development of SPIRIT-Children and Adolescents (SPIRIT-C) 2026

Note: Adjustments listed below are the same between *SPIRIT-Children and Adolescents* (SPIRIT-C) *2026* and *CONSORT-Children and Adolescents* (CONSORT-C) *2026*

- In the protocol publication,[1] we refer to the most recent updates of the SPIRIT and CONSORT checklists as the "2023 version"; however, the SPIRIT and CONSORT updates were still ongoing at the time. We closely followed the development of the SPIRIT | CONSORT-C updates, and used the most recent versions, i.e., the published versions from 2025.[2 3]
- The protocol states that young people ages 12-24 years will be involved in the SPIRIT-C 2026 and CONSORT-C 2026 development and describes the rationale behind this selected age range. In short, this range is based on the World Health Organization (WHO)'s definition of young people, and the age ranges of members of the involved Young Persons Advisory Groups (YPAGs). As the project continued, we modified the target age group to accommodate young people ages 10-24 years as some of the participating YPAG's membership evolved to also include young people as young as 10 years old.
- Though we planned to include family caregivers outside of Canada in the international Delphi study, despite our recruitment efforts through our networks, only family caregivers from Canada signed up to be a Delphi panellist. This is detailed in the limitations.
- We did not formally implement the Public Involvement Impact Assessment Framework (PiiAF)[4] to develop an impact assessment plan as per the protocol. We did consider and integrate key elements of the PiiAF (e.g., values, approaches, research focus/design, practical issues, and impacts of public involvement) while we collaborated with several key partners with extensive experience in formulating a meaningful strategy to involve young people and family caregivers in the development of SPIRIT-C 2026 and CONSORT-C 2026. As we describe in the Statement paper, we closely followed and implemented the published "blueprint" recommendations for patient and public involvement in reporting guideline development.[5] We documented the application and use of each of these 17 recommendations, prospectively collected feedback from young people and family caregivers after each project stage they were involved with, and noted their impact on the project. Details are presented in a separate publication.[6]
- In the Delphi study, panellists rated the candidate reporting items labelled as "Base item" or "SPIRIT/CONSORT-Outcomes item" on a 3-point scale: "No, exclude", "Unsure", and "Yes, keep". We used this 3-point scale for these items, as these had already been voted on through a consensus process in prior projects. For all candidate reporting items, we offered an "I'm opting out" option.
- During Delphi Round 1, some panellists expressed concerns over the guideline including items that are *relevant* but not necessarily *specific* to paediatric trials. After review of the relevance and specificity of each candidate reporting item, from Round 2 onwards, we labelled each item as either *specific (S)* or *relevant (R)* for paediatric trials. To limit the number of new reporting items, we removed several candidate *relevant (R)* items from consideration as a standalone reporting item and instead incorporated them as "paediatric detail" in the E&E document. Details are given in the main Statement text.
- In the protocol, we described how we planned to reach out to paediatric clinical trialists from Clinical Trials.gov to identify pilot testers; however, we reached out to colleagues and networks of the Core Project Team, existing international paediatric trial networks, and paediatric research organizations instead. This is detailed in the limitations.

- Though we decided that a two-day final project meeting with key contributors was not needed, as detailed in the main Statement text, we held a final Core Project Team meeting prior to finalisation of the guidelines to review and discuss all written feedback from co-authors and pilot testers.

eAppendix 2. Contributors to the Development of SPIRIT-Children and Adolescents (SPIRIT-C) 2026

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*Indicates those who completed all three rounds of the Delphi study.
†Indicates those who attended the Consensus Meeting.

eAppendix 3. Detailed Methods

Generation of candidate reporting items

In developing a list of candidate reporting items for SPIRIT-C 2026, we first reviewed a confidential copy of the recently published SPIRIT 2026 items and CONSORT 2026 items.[2 3] We also reviewed the "base checklist", which contained reporting items informed by a 2015 systematic review,[7] conducted as part of the initial development effort of the SPIRIT-C 2026 and CONSORT-C 2026 extensions. Then, a Core Project Team member (AB) reviewed literature, articles, and various clinical trial reporting guidance documents to identify additional candidate reporting items. Specifically, we reviewed recent paediatric literature and SPIRIT and CONSORT extensions published as of July 2023 to identify additional candidate items and to explore whether any existing items needed modification or removal. Using Google Scholar and Google Search, we looked for articles regarding *reporting in pediatric clinical trials*, *clinical trial reporting in children*, *pediatric clinical trial reporting guidelines*, and *pediatric trial reporting guidelines* from April-August 2023. We also searched on OVID Medline to identify additional articles from January 2014 – September 1, 2023 (**eAppendix 4,** Web Appendix 1), and reviewed articles and regulatory guidance documents received from the paediatric trial experts we engaged during project meetings. In this process, we considered emerging topics, such as patient and family engagement during various trial stages, and the value of sharing "post-trial next steps" with participants – raised by youth and parents during the development of a recently developed "plain language trial results communication template" called CommuniKIDS.[8] These efforts resulted in the generation of the preliminary list of candidate reporting items, which contained original and modified items from the "base checklist" and newly generated items based on the literature search.

Simultaneously, additional candidate reporting items were generated by young people who contributed to two Young Person Reporting Guideline (YPRG) workshops, held between December 2023 and January 2024 in five countries: Canada, England, France, Scotland, and Spain. Each virtual YPRG workshop was conducted by the Young Person Advisory Group (YPAG) in each respective country by their youth facilitators (see acknowledgments). In Canada, the workshops were attended by interested Youth Advisory Group members and other young people from various Canadian YPAGs. All discussion points from each workshop were reviewed to identify potential new candidate reporting items that could be included in the Delphi Study for voting. New candidate items suggested by youth at the workshop were considered "Youth Generated". Candidate items suggested by the youth at the workshops already in the existing candidate item list were classified as "Youth Endorsed". Further details on the YPRG workshops are described in a separate publication.[6]

The candidate reporting items list was reviewed by two members of the Core Project Team (AB, MO), who added paediatric-trial-relevant items from existing SPIRIT and CONSORT extensions. Candidate reporting items were placed within the framework of the SPIRIT and CONSORT 2026 checklists,[2 3] which were reviewed and refined by members of the Core Project Team, resulting in the Delphi Round 1 candidate reporting item list.

International Delphi Study

An online international Delphi study was conducted from January to May 2024 with the aim to reduce the number of candidate reporting items and to reach consensus on a "minimum set" of essential items. We developed the Delphi surveys using the Research Electronic Data Capture (REDCap) platform.[9] The Delphi study was designed so panellists were able to vote on candidate items for both SPIRIT-C 2026 and CONSORT-C 2026, thus streamlining the process of considering the importance and relevance of items to both checklists.

Core Project Team members were not eligible to participate as Delphi panellists. We identified potential Delphi panellists internationally with the relevant expertise and knowledge of paediatric RCTs and trial methods through the contacts and research networks of the Core Project Team and International Advisory Group, collaborators from past methodology projects, and steering committee members and authors of the Standards for Child Health (StaR).[10 11] We also expanded our reach globally through snowball sampling, and encouraged those who registered to be a Delphi panellist to also forward the invitation to their colleagues and networks with relevant expertise. We directly reached out to the editors from *JAMA Pediatrics*, *The Lancet Child and Adolescent Health*, *Archives of Disease in Childhood*, *Pediatrics*, and *Journal of Pediatrics,* inviting them to join the Delphi study as panellists.

To maximize diversity in the representation of roles, expertise, and geographic locations, we created a general online interest form for experts involved in paediatric RCTs to indicate their interest in contributing to the project. This form was circulated at academic conferences (44th Annual Society for Clinical Trials Meeting (2023), Maternal Infant Child and Youth Research Network (MICYRN) Annual Retreat 2023). In December 2023, we published a Viewpoint article in JAMA Pediatrics,[12] where readers were invited to fill out the general interest form if they wanted to be involved in the development of the SPIRIT-C 2026 and CONSORT-C 2026 extensions.

All interested in being a Delphi panellist completed a registration form to provide professional background information and details on their relevant expertise. Individuals were eligible to contribute as a Delphi panellist if they had experience in at least one of the following: a) authoring or reviewing paediatric trial protocols or reports; b) conducting systematic reviews/evidence synthesis of paediatric trials; c) designing and/or statistical planning of paediatric trials; d) developing reporting guidelines relevant to paediatric trials and/or core outcome sets; or e) consulting paediatric trial literature to inform clinical-decision making.

In addition, we invited young people (eligible ages 19-24 years) and family caregivers with lived experience related to paediatric RCTs (e.g., personal experience as paediatric trial participants or of their child, users of paediatric RCT protocols or reports) to be a Delphi panellist.[6] Advisors in the FCAG facilitated the identification of young people and family caregivers through various existing patient partner and research groups, including the Family Leader Program at the Children's Hospital of Eastern Ontario (CHEO), the Canadian PKU and Allied Disorders (CanPKU+), and the Youth Engagement in Research Instagram account (@youth_in_research). We also reached out to patient partners who were active within research groups in Canada, including INFORM RARE, Centre for Addiction and Mental Health (CAMH) National Youth Advisory Council (NYAC), Maternal Infant Child and Youth Research Network (MICYRN) KidsCan Young Persons' Advisory Group (YPAG), SickKids Pain Centre Patient Advisory Committee, Pediatric Outcome Improvement through Coordination of Research Networks (POPCORN), Solutions for Kids in Pain (SKIP), Winnipeg Advisory Group, and TARGet! Kids. Each group facilitated the process by circulating the *Delphi study information and registration form* to members of their networks. We conducted a 1-hour virtual onboarding session with all young people and family caregivers who were interested in completing the Delphi study to provide them with information on the project and their role as a Delphi panellist.

Prior to the launch of Delphi Round 1 and Round 2, we pilot tested the online survey. Round 1 was piloted by a family advisor, research fellow, two PhD students, and three research staff. Round 2 was piloted by two family advisors. We conducted pilot testing to ensure that the Delphi survey instructions, format, and glossary were clear, understandable, and functioned properly. Pilot testers included individuals with no background in research methods, and those with experience and expertise regarding Delphi studies or the development of reporting guidelines. All feedback that we received from pilot testers was reviewed and implemented prior to launch of each round and informed the estimate that the survey could be completed

in about one hour. We did not pilot test Round 3 as the instruction and format were similar but shorter than Round 2.

Registered Delphi panellists were e-mailed the Delphi survey link. In total, we sent panellists two reminders for each round: one approximately 10 days prior to the survey closing date, and the another in the last week; reminders were only sent to those who have not yet completed the round. Between each Delphi round, there was a 3–4-week gap when the Core Project Team analysed the results and developed the next Delphi round. The team was available to provide support and answer questions or concerns from any panellist throughout the Delphi study. We offered an optional virtual check-in session for the contributing young people and family caregivers after Round 1.

In the Delphi survey, panellists were asked to rate each candidate item on its importance of reporting in a paediatric RCT protocol or report, the clarity of the item wording, and a free-text box, where they could comment on wording, suggest improvements, division of or merging of items, or explain their vote. The voting options presented were different depending on the classification of the reporting item. For a) "Base items", reporting items identified from the initial SPIRIT | CONSORT-C development efforts, and b) "SPIRIT | CONSORT-Outcomes items", items from the SPIRIT | CONSORT-Outcomes 2022 checklists,[13 14] panellists were asked to vote on a nominal scale of "No, exclude", "Unsure", or "Yes, keep", as these items had undergone a consensus process in previous projects. For c) "New/modified items", the new candidate reporting items from the literature search, panellists voted on a 9-point Likert scale, with ratings of 1-3 indicating *limited importance* for the item's inclusion, 4-6 indicating *important but not critical*, and 7-9 indicating *critical* for inclusion. For wording clarity, panellists were asked to vote on a 5-point bipolar Likert scale (Strongly disagree, Disagree, Neutral, Agree, Strongly Agree). If panellists did not want to vote for a particular item, panellists could select "I'm opting out".

We applied the following consensus criteria, as detailed in the protocol[1]: for an item to meet consensus criteria to be included, it had to be voted on a minimum of two times, ≥70% votes for "Yes, keep" or scores of 7-9, with <15% voting for exclusion. For an item to meet consensus criteria to be included, an item had to be voted a minimum of two rounds with, ≥70% votes for "No, excluded" or scores of 1-3, with <15% voting for inclusion. These criteria were followed for all items except for "Base items" and "SPIRIT | CONSORT-Outcomes" items, as these items had previously been voted on and undergone a consensus process in other projects. Therefore, if a "Base" or "SPIRIT | CONSORT-Outcomes" item met the inclusion criteria in Round 1, it was used as reaffirmation of their importance and was no longer included for voting in subsequent rounds.

In Round 2, panellists voted on candidate reporting items from Round 1 for a second time, along with suggested items from panellists in Round 1, and items generated during the YPRG workshops (see above). In this round, panellists also voted on three contenders for the reporting guidelines' final name and could suggest other options. Round 3 consisted of voting on candidate reporting items that have not yet been voted on at least twice.

After the completion of each round, the project lead (AB) calculated the voting frequencies for each reporting item for all panellists and for each key subgroup (i.e., academia, non-academic healthcare, family caregivers, and young people). We reviewed the written feedback and comments from all panellists, and summarized comments based on arguments for or against inclusion. Suggestions to improve item wording were reviewed and applied; modified items were put up for voting in the next round. We only included data from panellists who had completed the entire survey and put together a summary report document after each round which we provided to all panellists in the next round.

Given that we invited panellists to complete subsequent rounds only if they had completed the prior round in full, in both Rounds 2 and 3, panellists were able to see details regarding the voting results from the previous round. The information they could see for each item included their own vote from the previous round, the frequency of votes from other panellists, and summarized, anonymized comments from other panellists. They were also able to see voting results by group for family caregivers and young people vs. other panellists' groups.

International Consensus Meeting

In June 2024, we held a virtual Consensus Meeting over Zoom. Over five hours, we discussed and voted on items that had not yet met consensus criteria to be included or excluded for both SPIRIT-C 2026 and CONSORT-C 2026, voted to finalise the guideline name, and to introduce the process for drafting the E&E paper. Attendees of the meeting included invited individuals from the following groups: Delphi panellists who completed all three rounds and had indicated interest and availability to attend, International Advisory Group members, International Youth Involvement Steering Committee, reporting guideline developers, and Core Project Team members. Two members of the Core Project Team (AB, MO) selected invitees to the meeting to maximize the diversity in the representation of roles, expertise, and geographic locations.

To enable meeting attendees to participate fully, we prepared and circulated a Pre-Consensus Meeting "Package" a week before the meeting. This package contained details on logistics, instructions, and background on each candidate reporting item up for discussion and voting. To facilitate Family Caregiver Advisors' active participation during the meeting, we held a dedicated preparatory meeting two days prior to the Consensus Meeting. The preparatory meeting went over the purpose of the Consensus Meeting, their role, how to contribute effectively, and to go over the E&E writing process in depth, with time for questions at the end.

The Consensus Meeting comprised eight sessions chaired by the Core Project Team members dedicated to the following topics: young people and family caregiver involvement, overview of the Delphi study results, final reporting guidelines' name options, two sessions discussing reporting items that did not yet reach consensus, group writing process of the E&E papers, "real time" group voting on the reporting items discussed, and next project steps. Voting at the Consensus Meeting included three options: "Include", "Exclude", or "Abstain"; at least 70% of votes was needed for an item to be considered to have met consensus criteria to be included or excluded. In the situation that the item did not reach consensus criteria during the meeting, select Core Project Team members (AB, MO) made an executive decision on the inclusion or exclusion of the item in the next project phase.

E&E Group Writing

The E&E is a pedagogical paper that provides the rationale and evidence for the inclusion of each reporting item, with at least one example of its optimal reporting. In preparing the E&E paper, we adopted a group writing approach. Everyone who attended the Consensus Meeting was invited to be part of the writing team. Writing team members drafted and reviewed explanatory text and identified good reporting examples for each item from July – August 2024. Regardless of whether they attended the Consensus Meeting, we invited all International Advisory Group members to be part of the process. They had the choice to be a writer/reviewer in the E&E writing team, or to review the drafted E&E papers, or not to be involved in the process.

E&E writing team members were free to select the reporting items they wanted to contribute to and in what capacity. We requested all writing team members to contribute to a minimum of five reporting items. All writing team members worked collaboratively on a shared online Google document. We provided

detailed instructions, pre-final checklists, PDFs of 50 paediatric RCTs published in 2022, and a list of key elements for each reporting item as a starting point.

After the writing/review process concluded, two members of the Core Project Team (AB, MO) reviewed and edited all drafted contributions by the writing team, drafted additional text, and identified additional reporting examples, which were then reviewed by colleagues and International Advisory Group members and other colleagues who volunteered to provide feedback. We reviewed all feedback received, made further edits, and finalised the E&E papers for use in pilot testing.

Pilot testing of checklist, E&E, and finalisation

Pilot testing of the SPIRIT-C 2026 reporting items and E&E papers between October – November 2024 assessed usability, feasibility, and acceptability of the guideline. Individuals were eligible to pilot test the guidelines if they were a) drafting, (re)submitting, or published a paediatric RCT protocol in 2023 or 2024, or b) peer reviewing (e.g. as a journal editor) a paediatric RCT protocol. Pilot testers were identified through paediatric trial networks and research organizations that we reached out to during the Delphi study, in addition to colleagues and networks of the Core Project Team.

Along with the online pilot testing survey link, pilot testers had access to the SPIRIT-C 2026 checklist and E&E paper. For each reporting item, respondents could indicate whether the item was relevant, clear and understandable, and reported in their protocol. Respondents could indicate whether they referred to the E&E paper to understand the reporting item, and if they did, whether the E&E paper was helpful'; they were invited to offer feedback on the item or E&E text.

Two Core Project Team members (AB, MO) independently analysed the pilot testing results and reviewed all suggestions for wording changes to items or the E&E text, then reached consensus on the final changes to be made and identified additional examples as needed.

All members of the Core Project Team met in December 2024 for the final project meeting to discuss paper content, publications, and dissemination. Subsequently, checklists were finalised, the present paper was drafted, and all co-authors contributed to the finalisation of all publications.

eAppendix 4. Literature search strategy

OVID Medline Search Terms (search date: September 1, 2023)

Search terms	**Yield**
1. pediatrics.mp. or exp Pediatrics/	99074
2. clinical trials.mp. or exp Clinical Trial/	1381605
3. reporting.mp.	278355
4. exp Randomized Controlled Trials as Topic/ or trial reporting.mp. or exp Clinical Trials as Topic/	384343
5. randomized clinical trial.mp.	40234
6. RCT.mp.	34875
7. 1 and 2 and 3 and 4 and 5 and 6	1
8. 1 and 3 and 4	96
9. limit 8 to yr=’2014 – Current’	50

Other searches (Google Scholar, Google Search):

April 20, 2023: “Pediatric trial reporting guidelines”, Google Scholar, Since 2023
May 12, 2023: “pediatric clinical trials reporting guidelines”, Google Search
May 18, 2023: “scoping review for trials with PPI”, Google Search
June 12, 2023: “clinical trial reporting children”, Google Scholar, Since 2023
June 12, 2023: “clinical trial reporting children”, Google Search
August 25, 2023: “reporting pediatric trials”, Google Search

eAppendix 5. Item flow in Delphi Rounds 1-3

We initially identified 32 candidate items to include for voting. After Round 1, three "Base items" met consensus criteria to be included, and based on the comments and results, we removed 3 redundant items and merged 2 items with existing items. One item was split into three separate items based on panellist feedback. Twelve items were carried over from Round 1 to Round 2 for voting, with some items modified based on panellist feedback and suggestions.

In our effort to be comprehensive, Round 1 contained reporting items that were specific to paediatric RCTs, and those that, while not specific to the paediatric context, were considered particularly relevant to paediatric RCTs. However, we received feedback from some panellists concerned with the feasibility of a paediatric reporting guideline that includes reporting items that are not specific to paediatric RCTs. Therefore, after Round 1, we reviewed each reporting item and classified them as either *specific* (S) or *relevant* (R) – each reporting item from Round 2 onwards were labelled accordingly for transparency. We removed most *relevant* (R) reporting items from consideration as standalone reporting items. Therefore, 12 items were removed from consideration as standalone reporting items after Round 1, as they were more appropriate as paediatric details within the E&E for existing SPIRIT 2025 items on topics such as patient and public involvement, interventions, outcomes, harms, participant enrolment, and post-trial care/provisions.

In Round 2, panellists were asked to vote on 23 items for SPIRIT-C 2026: the 12 items carried over from Round 1, five Youth Generated items from the YPRG workshops, two panellist-suggested items from Round 1, two items that resulted from an item split, and two items originally considered for CONSORT-C 2026 only but also found appropriate for SPIRIT-C 2026 from Round 2 onwards. Round 2 resulted in four items meeting consensus criteria to be included. Six items were removed: one redundant, and five items deemed more suitable as E&E detail. Five items did not meet consensus criteria to be included or excluded after being voted on in Rounds 1 and 2 and were carried over for discussion at the Consensus Meeting. Panellist comments led to rewording of select items.

In Round 3, we presented only reporting items *specific* to paediatric RCTs to our panellists. Eight candidate items pertaining to SPIRIT-C 2026 were voted on by panellists. Three items consensus criteria to be included, and five items did not. Combined with the five items that did not meet consensus criteria to be included or excluded after Round 2, 10 total items pertinent to SPIRIT-C 2026 were carried over to be discussed at the Consensus Meeting. At the conclusion of the Delphi study, 10 items met consensus criteria to be included for SPIRIT-C 2026.

eTable 1. Characteristics of Delphi panellists

Characteristics	Round 1 (N = 176)	Round 2 (N = 144)	Round 3 (N = 143)
Panellist identification	**N (%)**	**N (%)**	**N (%)**
Self-selected/part of the snowball process	104 (59)	77 (53)	77 (54)
Invited by the team	72 (41)	67 (47)	66 (46)
Primary perspective	**N = 176**	**N = 144**	**N = 143**
Academia	132 (75)	106 (74)	105 (74)
Non-academic healthcare	16 (9)	12 (8)	12 (8)
Family caregiver (e.g., parent, guardian)	10 (6)	10 (7)	10 (7)
Non-profit	5 (3)	4 (3)	4 (3)
Young person (ages 19-24)	4 (2)	4 (3)	4 (3)
Regulatory agency	1 (1)	1 (1)	1 (1)
Industry	1 (1)	1 (1)	1 (1)
Other[a]	7 (4)	6 (2)	6 (2)
Location	**N = 176**	**N = 144**	**N = 143**
Europe	92 (52)	68 (47)	68 (47)
North America	63 (36)	57 (40)	56 (40)
South America	1 (1)	1 (1)	1 (1)
Oceania	8 (5)	7 (5)	7 (5)
Asia	8 (5)	7 (5)	7 (5)
Africa	2 (1)	2 (1)	2 (1)
Middle East	2 (1)	2 (1)	2 (1)
Highest level of education[b]	**N = 162**	**N = 130**	**N = 129**
MD (Medical degree) & PhD	69 (43)	53 (41)	53 (41)
MD (Medical degree)	31 (19)	27 (20)	26 (20)
PhD	37 (23)	31 (24)	31 (24)
Master's degree	17 (10)	12 (9)	12 (9)
Bachelor's degree	3 (2)	2 (2)	2 (2)
Other[c]	5 (3)	5 (4)	5 (4)
Interest-holder group[d]	**N = 176**	**N = 144**	**N = 143**
Child health researcher	95 (54)	79 (55)	78 (55)
Paediatrician	83 (47)	70 (49)	69 (48)
Paediatric/child health trial protocol author	82 (47)	68 (47)	67 (47)
Paediatric/child health clinician scientist	77 (44)	62 (43)	61 (43)
Paediatric/child health trial report author	71 (40)	60 (42)	59 (41)
Paediatric/child health clinical trialist	69 (39)	59 (41)	58 (41)
Systematic review author	68 (39)	57 (40)	56 (39)
Journal editor	41 (23)	37 (26)	37 (26)
Reporting guideline developer	20 (11)	15 (10)	15 (10)
Methodologist	33 (19)	26 (18)	25 (17)
Epidemiologist	31 (18)	28 (19)	28 (20)
Research ethics committee member that reviews trial protocols	22 (13)	20 (14)	20 (14)
Core outcome set developer	16 (9)	13 (9)	13 (9)
Biostatistician	13 (7)	12 (8)	12 (8)
Family caregiver (e.g., parent, guardian)	10 (6)	10 (7)	10 (7)
Student of trainee working on a paediatric/child health clinical trial	7 (4)	6 (4)	6 (4)
Young people (ages 19-24)	4 (2)	4 (3)	4 (3)
Funder	1 (1)	1 (1)	1 (1)

Paediatric specialty[e]	**N = 106**	**N = 87**	**N = 86**
Adolescent Medicine	1 (1)	0 (0)	0 (0)
Allergology	1 (1)	1 (1)	1 (1)
Anaesthesia	1 (1)	1 (1)	1 (1)
Community Paediatrics	1 (1)	1 (1)	1 (1)
Critical/Intensive Care	3 (3)	3 (3)	3 (4)
Epidemiology	1 (1)	1 (1)	1 (1)
General Paediatrics	4 (4)	4 (5)	4 (5)
Hepatology	1 (1)	1 (1)	1 (1)
Hospital Paediatrics	1 (1)	1 (1)	1 (1)
Infectious Disease	7 (7)	5 (6)	5 (6)
Neonatology	26 (25)	22 (26)	22 (26)
Neurodevelopment	1 (1)	1 (1)	1 (1)
Neurorehabilitation	1 (1)	1 (1)	1 (1)
Orthopaedic Surgery	1 (1)	1 (1)	1 (1)
Emergency medicine	9 (9)	8 (9)	7 (8)
Gastroenterology	6 (6)	4 (5)	4 (5)
Oncology	2 (2)	2 (2)	2 (2)
Cardiology	1 (1)	1 (1)	1 (1)
Nephrology	2 (2)	2 (2)	2 (2)
Neurology	4 (4)	3 (3)	3 (3)
Psychiatry	2 (2)	2 (2)	2 (2)
Pharmacology	1 (1)	1 (1)	1 (1)
Psychology	1 (1)	1 (1)	1 (1)
Respirology/Pulmonology	4 (4)	3 (3)	3 (3)
Rheumatology	2 (2)	2 (2)	2 (2)
Other[f]	22 (21)	15 (17)	15 (17)
Level of expertise on paediatric/child health clinical trials[b,g]	**N = 162**	**N = 130**	**N = 129**
High	93 (57)	76 (58)	75 (58)
Average	63 (39)	50 (38)	50 (39)
Low	6 (4)	4 (3)	4 (3)
Level of expertise on the SPIRIT statement[b,h]	**N = 162**	**N = 130**	**N = 129**
High	37 (23)	30 (23)	29 (22)
Average	91 (56)	76 (58)	76 (59)
Low	34 (21)	24 (18)	24 (19)
Level of expertise on the CONSORT statement[b,i]	**N = 162**	**N = 130**	**N = 129**
High	62 (38)	55 (42)	54 (42)
Average	85 (52)	68 (52)	68 (53)
Low	15 (9)	7 (5)	7 (5)
Number of paediatric/child health trial reports written/co-authored[b]	**N = 162**	**N = 130**	**N = 129**
None	26 (16)	18 (14)	18 (14)
< 3	50 (31)	41 (32)	41 (32)
3-6	40 (25)	29 (22)	29 (22)
7-10	16 (10)	15 (12)	15 (12)
>10	30 (18)	27 (21)	26 (21)
Number of paediatric/child health trial protocols written/co-authored[b]	**N = 162**	**N = 130**	**N = 129**
None	24 (15)	18 (14)	18 (14)
< 3	57 (35)	45 (35)	45 (35)
3-6	46 (28)	38 (29)	38 (29)
7-10	10 (6)	8 (6)	8 (6)

>10	25 (15)	21 (16)	20 (16)
Number of paediatric/child health trials conducted	**N = 162**	**N = 130**	**N = 129**
None	24 (15)	20 (15)	20 (15)
< 3	45 (28)	35 (27)	35 (27)
3-6	38 (23)	28 (22)	28 (22)
7-10	20 (12)	16 (12)	16 (12)
>10	35 (22)	31 (24)	30 (24)
Number of paediatric/child health trial reports reviewed for funding agency or medical journal[b]	**N = 162**	**N = 130**	**N = 129**
None	27 (17)	18 (14)	18 (14)
< 3	25 (15)	19 (15)	19 (15)
3-6	31 (19)	29 (22)	29 (22)
7-10	20 (12)	16 (12)	16 (12)
>10	59 (36)	48 (37)	47 (37)
Number of paediatric/child health trial protocols reviewed for a funding agency or medical journal[b]	**N = 162**	**N = 130**	**N = 129**
None	33 (20)	23 (18)	23 (18)
< 3	32 (20)	27 (21)	27 (21)
3-6	40 (25)	34 (26)	34 (26)
7-10	21 (13)	16 (12)	16 (12)
>10	36 (22)	30 (23)	29 (23)
Number of paediatric/child health trials involved in the design and/or statistical planning of[b]	**N = 162**	**N = 130**	**N = 129**
None	13 (8)	11 (8)	11 (8)
< 3	54 (33)	42 (32)	42 (32)
3-6	34 (21)	26 (20)	26 (20)
7-10	23 (14)	18 (14)	18 (14)
>10	38 (23)	33 (25)	32 (25)
Number of core outcome sets developed and/or co-authored[b]	**N = 162**	**N = 130**	**N = 129**
None	73 (45)	55 (42)	54 (42)
< 3	48 (30)	38 (29)	38 (29)
3-6	23 (14)	21 (16)	21 (16)
7-10	8 (5)	7 (5)	7 (5)
>10	10 (6)	9 (7)	9 (7)
Number of reporting guidelines relevant to trials developed and/or co-authored[b]	**N = 162**	**N = 130**	**N = 129**
None	95 (59)	71 (55)	71 (55)
< 3	47 (29)	41 (32)	40 (32)
3-6	12 (7)	11 (8)	11 (8)
7-10	6 (4)	6 (5)	6 (5)
>10	2 (1)	1 (1)	1 (1)
Number of systematic reviews and/or evidence synthesis of trials conducted[b]	**N = 162**	**N = 130**	**N = 129**
None	38 (23)	26 (20)	26 (20)
< 3	47 (29)	37 (28)	37 (28)
3-6	40 (25)	33 (25)	33 (25)
7-10	14 (9)	14 (11)	14 (11)
>10	23 (14)	20 (15)	19 (15)
Frequency of reading and/or consulting trial literature to inform clinical decision-making practices[b]	**N = 162**	**N = 130**	**N = 129**
Never	4 (2)	2 (1)	2 (1)

Occasionally	17 (10)	13 (8)	13 (8)
Often	128 (79)	104 (64)	103 (64)
Not applicable	13 (8)	11 (7)	11 (7)

[a] Other consisted of those who indicated: publishing (n = 1), academia and regulatory agency (n = 1), associate editor and chair of paediatrics (n = 1); paediatric emergency medicine (n = 1); student and person with a paediatric-onset rare disease (n = 1); healthcare with academia (n = 1); ethics committee (n = 1). Panellist who indicated ethics committee did not complete Rounds 2 and 3.

[b] Denominator excludes family caregivers (n = 10) and young people (ages 19-24) (n = 4). Round 1 (n = 162); Round 2 (n = 130); Round 3 (n = 129).

[c] PharmD/PhD; Clinical Doctorate; MBBS; MBChB; MRCP, MRCPCH

[d] Panellist could select more than one option, so percentages do not add up to 100%

[e] Limited to those who selected “paediatrician” or “clinician-scientists” as their interest-holder groups (Round 1: n = 106; Round 2: n = 87; Round 3: n = 86)

[f] Other consisted of a mix of specialties: all trials/anaesthesia (n = 1, Round 1); allergy and immunology (n = 2, Round 1; n = 1, Rounds 2-3); infectious diseases and immunology (n = 1, Rounds 1-3); infectious diseases and pulmonology (n = 1, Round 1); inherited genetic conditions, emergency medicine (n = 1; Rounds 1-3); n/a (n = 1, Rounds 1-3); neonatal intensive care nurse, advanced neonatal nurse practitioner (n = 1, Round 1); neonatology and clinical pharmacology (n = 1, Rounds 1-3); neurodisability, child protection (n = 1, Rounds 1-3); paediatric and neonatal intensive care (n = 1, Round 1); paediatric gastroenterology, hepatology, and nutrition (n = 2, Round 1; n = 1, Rounds 2-3); paediatric nephrologist, clinical pharmacologist, and clinical trials lead (n = 1, Rounds 1-3); paediatric oncology, child health outcomes (n = 1, Round 1); paediatrics, paediatric cardiology (n = 1, Rounds 1-3); paediatric critical care and clinical pharmacology (n = 1, Rounds 1-3); pharmacovigilance and drug safety (n = 1, Rounds 1-3); pulmonology and allergology (n = 1, Rounds 1-3); respiratory and high dependency care (n = 1, Rounds 1-3); respiratory and sleep medicine (n = 1, Rounds 1-3); rheumatology, physiology (n = 1, Rounds 1-3)

[g] Panellists’ self-rated expertise (e.g., designing, conducting, reporting, understanding, and using) paediatric/child health clinical trials

[h] Panellists’ self-rated expertise on using the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement

[i] Panellists’ self-rated expertise on using the Consolidated Standards of Reporting Trials (CONSORT) statement

eTable 2. Characteristics of Consensus Meeting panellists

Name[a]	**Title(s)**	**Institution(s)**	**Location**	**Self-reported interest-holder group**
Ami Baba, MRes	**Project Lead,** SPIRIT | CONSORT-C project **Senior Project Manager,** The Hospital for Sick Children	The Hospital for Sick Children	Canada	Trial protocol author Trial report author Child health researcher Reporting guideline developer Systematic review author
Martin Offringa, MD, PhD	**Project Principal Investigator,** SPIRIT | CONSORT-C project **Senior Scientist,** Staff Neonatologist **Associate editor,** Cochrane Neonatal	The Hospital for Sick Children	Canada	Trial report author Trial protocol author Child health researcher Clinical trialist Clinician-scientist Paediatrician Reporting guideline developer Core outcome set developer Methodologist Epidemiologist Journal editor Systematic review author
Karel Allegaert, MD, PhD	**Professor,** KU Leuven **Senior consultant,** Erasmus MC Rotterdam **Associate Editor**, Archives of Disease in Childhood **Associate Editor,** Archives of Disease in Childhood – Fetal and Neonatal Edition **Deputy Editor in Chief,** BMJ Paediatrics Open	KU Leuven, Eramus MC, Rotterdam	Belgium, the Netherlands	Trial protocol author Trial report author Clinical trialist Clinician scientist Child health researcher Neonatologist, Clinical Pharmacologist Reporting guideline developer Core outcome set developer Journal editor Systematic review author
Katelynn E. Boerner, PhD RPsych	**Assistant Professor,** University of British Columbia & BC Children's Hospital Research Institute **Registered Psychologist,** BC Children's Hospital	University of British Columbia	Canada	Trial protocol author Trial report author Clinician scientist Child health researcher Journal editor Systematic review author

Name[a]	Title(s)	Institution(s)	Location	Self-reported interest-holder group
Nancy J. Butcher, PhD	**Co-Director,** Increasing Capacity for Maternal and Paediatric Trials (IMPaCT) **Assistant Professor,** University of Toronto	The Hospital for Sick Children	Canada	Trial protocol author Trial report author Clinical trialist Child health researcher Reporting guideline developer Core outcome set developer Methodologist Systematic review author
Tanya Chute Nagy	**Family Caregiver Advisor,** SPIRIT | CONSORT-C project **Vice President,** Canadian PKU and Allied Disorders (CanPKU+)	Canadian PKU and Allied Disorders (CanPKU+)	Canada	Family caregiver
Jérémie F. Cohen, MD, PhD	**Professor,** Necker Hospital for Sick Children	Necker Hospital for Sick Children, Université Paris Cité, France	France	Paediatrician Reporting guideline developer Methodologist Epidemiologist Journal editor Systematic review author
Kimberly Courtney, MSc, CCLS, RECE	**Family Caregiver Advisor,** SPIRIT | CONSORT-C project **Family Engagement in Research Facilitator**, Child Life Specialist, CHEO	CHEO	Canada	Family caregiver
Yan Défossés	**Family Caregiver Advisor,** SPIRIT | CONSORT-C project	N/A	Canada	Family caregiver
Amanda Doherty-Kirby, PhD	**Family Caregiver Advisor,** SPIRIT | CONSORT-C project	N/A	Canada	Family caregiver
Reinhard Feneberg, MD	**Medical Director,** ICON plc	ICON Plc	Germany	Trial protocol author Trial report author Clinician-scientist Child health researcher Paediatrician Biostatistician

Name[a]	Title(s)	Institution(s)	Location	Self-reported interest-holder group
Ségolène Gaillard	**Project Manager,** Hospices Civils de Lyon **PhD Student,** Claude Bernard University	Hospices Civils de Lyon eYPAGnet	France	Member of the Youth Involvement International Steering Committee
Lisa Hartling, PhD	**Professor,** University of Alberta **Director**, Alberta Research Centre for Health Evidence (ARCHE) **Canada Research Chair,** Knowledge Synthesis and Translation	University of Alberta	Canada	Trial protocol author Trial report author Clinical trialist Child health researcher Reporting guideline developer Methodologist Epidemiologist Systematic review author
Terry P. Klassen, MD	**Provincial Department Head of Paediatrics,** University of Saskatchewan **Adjunct Professor**, University of Manitoba	University of Saskatchewan	Canada	Trial protocol author Trial report author Clinical trialist Clinician scientist Child health researcher Paediatrician Methodologist Systematic review author
Niina Kolehmainen, PhD	**Professor in Child Health Research,** Newcastle University	Newcastle University	UK	Trial protocol author Allied health clinician Child health researcher Systematic review author
Menelaos Konstantinidis, MSc	**PhD Student,** University of Toronto **Chief Statistician,** Emory University School of Medicine	St. Michael's Hospital, Unity Health Toronto	Canada	Child health researcher Reporting guideline developer Methodologist Biostatistician Epidemiologist Journal editor Systematic review author Student/trainee
Thierry Lacaze-Masmonteil, MD, PhD	**Scientific Director,** Maternal Infant and Child Youth Research Network (MICYRN)	Maternal Infant and Child Youth Research Network (MICYRN)	Canada	Clinician scientist
Esther Lau, MA	**Editor-in-Chief,** The Lancet Child & Adolescent Health	The Lancet Child & Adolescent Health	UK	Journal editor

Name[a]	Title(s)	Institution(s)	Location	Self-reported interest-holder group
Patricia Longmuir, PhD	**Senior Scientist,** CHEO Research Institute	CHEO Research Institute	Canada	Trial protocol author Trial report author Child health researcher
Kayur Mehta, MD	**Assistant Scientist,** Johns Hopkins Bloomberg School of Public Health	Johns Hopkins University	USA	Trial protocol author Trial report author Clinical trialist Clinician scientist Child health researcher Paediatrician Epidemiologist Systematic review author
David Moher, PhD	**Professor,** University of Ottawa	University of Ottawa	Canada	Clinical epidemiologist Reporting guidelines Publication scholarship
Shaun Morris, MD	**Senior Scientist and Infectious Disease Physician,** The Hospital for Sick Children	The Hospital for Sick Children	Canada	Trial protocol author Trial report author Clinical trialist Clinician scientist Child health researcher Paediatrician Systematic review author
Begonya Nafria Escalera, PhD Candidate	**Head of the Patient Engagement in Research Department,** Institut de Recerca Sant Joan de Deu **PhD Student,** Universitat Internacional de Catalunya	Institut de Recerca Sant Joan de Deu eYPAGnet	Spain	Member of the Youth Involvement International Steering Committee Patient involvement expert Systematic review author
Kim An Nguyen, MD, PhD	**Associate Professor, Neonatologist,** Hospices Civils de Lyon Claude Bernard University Lyon 1	Hospices Civils de Lyon LBBE/Claude Bernard University Lyon 1	France	Trial protocol author Trial report author Clinical trialist Clinician scientist Paediatrician Methodologist Epidemiologist Systematic review author Research ethics committee member
Michal Odermarsky, MD, PhD	**Senior Pediatric Cardiologist,** Children Heart Centre, Skane University Hospital	Children Heart Centre, Skane University Hospital	Sweden	Trial protocol author Child health researcher Paediatrician

Name[a]	Title(s)	Institution(s)	Location	Self-reported interest-holder group
Wes Onland, MD, PhD	**Neonatologist,** Emma Children's Hospital, Amsterdam UMC	Emma Children's Hospital, Amsterdam UMC	The Netherlands	Trial protocol author Trial report author Clinical trialist Clinician scientist Paediatrician Systematic review author
Ramesh Poluru, PhD	**Senior Program Officer,** The INCLEN Trust International	The INCLEN Trust International	India	Trial protocol author Trial report author Clinical trialist Child health researcher Methodologist Biostatistician Epidemiologist Journal editor
Beth Potter, PhD	**Professor,** University of Ottawa **Co-Investigator**, SPIRIT | CONSORT-C project	University of Ottawa	Canada	Epidemiologist Child Health Researcher Trial protocol author Systematic review author
Jennifer Preston, PhD Candidate, BA Hons	**Patient and Public Involvement Policy Manager**	University of Liverpool eYPAGnet	UK	Member of the Youth Involvement International Steering Committee Patient and Public Involvement Expert Systematic review author
Diane Purper-Ouakil, MD, PhD	**Professor,** University Hospital of Montpellier **Head of Child and Adolescent Psychiatry Department,** University Hospital of Montpellier	University Hospital of Montpellier	France	Clinician scientist Clinical trialist Trial protocol author Systematic review author
Giorgio Reggiardo, PhD	**Head of Biostatistics Unit,** TEDDY European Network of Excellence for Paediatric Research	TEDDY European Network of Excellence for Paediatric Research	Italy	Methodologist Biostatistician Epidemiologist Systematic review author
Amy Slogrove, MD PhD	**Senior Editor,** The Lancet Child & Adolescent Health	The Lancet Child & Adolescent Health	South Africa	Paediatrician Epidemiologist Journal editor
Maureen Smith, MEd	**Patient Engagement Expert,** SPIRIT | CONSORT-C project	N/A	Canada	Patient Partner

Name[a]	Title(s)	Institution(s)	Location	Self-reported interest-holder group
Catherine Stratton, MPH	**PhD Student,** University of Toronto	University of Toronto	Canada	Student/trainee
Alene Toulany, MD	**Adolescent Medicine Specialist,** The Hospital for Sick Children	The Hospital for Sick Children	Canada	Paediatrician
Julia Upton, MD, MPH	**Clinical Immunologist & Allergist**	The Hospital for Sick Children	Canada	Trial protocol author Trial report author Clinical trialist Child health researcher Paediatric subspecialist Journal editor Systematic review author

[a]SPIRIT | CONSORT-Children and Adolescents team members also in attendance to facilitate meeting: Adrian Sammy (notetaker)
Note: The consensus meeting was held virtually on 20 June 2024.

eTable 3. Characteristics of Pilot Testers

Self-reported characteristics	**SPIRIT-C 2026 Pilot testers (n = 22)**
Location	**N (%)**
Canada	6 (27)
France	4 (18)
The Netherlands	4 (18)
Italy	3 (14)
Australia	3 (14)
Belgium	1 (4)
United Kingdom	1 (4)
Highest level of education	
MD (Medical degree) & PhD	7 (32)
PhD	7 (32)
MD (Medical degree)	3 (14)
Master's degree	4 (18)
Bachelor's degree	1 (4)
Participated in the Delphi study	
Yes	5 (23)
No	17 (77)
Participated in the Explanation and Elaboration (E&E) Writing Process	
Yes	4 (18)
No	18 (82)
Use of the guideline*	
As a checklist	17 (77)
As a writing tool	9 (41)
As a peer review or assessment of someone else's trial report	4 (18)
As a teaching tool	4 (18)
Trial protocol used for pilot testing	
Published	6 (27)
Not yet published	16 (73)
Role in trial protocol used for pilot testing	
First author	10 (45)
Principal investigator/senior author	7 (32)
Co-author	4 (18)
Peer reviewer	1 (4)
Trial protocol specialty	
Neonatology	4 (18)
Psychiatry	3 (14)
Haematology	3 (14)
Neurology	3 (14)
Rehabilitation	1 (4)
Ophthalmology	1 (4)
Rare diseases	1 (4)
Endocrinology	1 (4)
Anaesthesia	1 (4)
Emergency medicine	1 (4)
Undisclosed	3 (14)

*Respondents were able to select more than one option, so percentages add up to over 100%

eTable 4. *SPIRIT-Children and Adolescents (SPIRIT-C) 2026* Expanded Checklist with Summary of Key Elements

Section/Topic	Item No.	SPIRIT 2025 Statement	Item No.	SPIRIT-Children and Adolescents (SPIRIT-C) 2026 extension	Summary of Key Elements
Administrative information					
Title and structured summary	1a	Title stating the trial design, population, and interventions, with identification as a protocol	1a.1*	Identify that it is a paediatric trial protocol, and include age group(s)/range(s), interventions, and, if applicable, trial acronym	• Clear indication it is a paediatric trial with relevant terms (e.g., paediatric, newborn, infants, children, young children, adolescents, etc.) • (Sub) population accompanied by age range(s) • Intervention(s) • Acronym, if used
	1b	Structured summary of trial design and methods, including items from the World Health Organization Trial Registration Data Set			
Protocol version	2	Version date and identifier			
Roles and responsibilities	3a	Names, affiliations, and roles of protocol contributors			
	3b	Name and contact information for the trial sponsor			
	3c	Role of trial sponsor and funders in design, conduct, analysis, and reporting of trial; including any authority over these activities			
	3d	Composition, roles, and responsibilities of the coordinating site, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable			
Open science					
Trial registration	4	Name of trial registry, identifying number (with URL), and date of registration. If not yet registered, name of intended registry			
Protocol and statistical analysis plan	5	Where the trial protocol and statistical analysis plan can be accessed			
Data sharing	6	Where and how the individual de-identified participant data (including data dictionary), statistical code, and any other materials will be accessible	6.1	Describe whether individual participant data will be shared with others not directly involved in the trial, and how the child/adolescent's and/or family's confidentiality will be respected within the study	• Whether individual participant data will be shared with others, or used in future projects • How shared trial data will be anonymized or de-identified • If participant data will be shared, measures taken to mitigate any possible risks associated with sharing • Whether participants can opt out of the sharing of their personal data, or specific information • The circumstances under which individual child data would be shared with their clinician/caregiver, why this is necessary and valuable, and steps taken to prevent harm associated with disclosure

Section/Topic	Item No.	SPIRIT 2025 Statement	Item No.	SPIRIT-Children and Adolescents (SPIRIT-C) 2026 extension	Summary of Key Elements
					• How study participants will be informed about data sharing methods and who will have access to the clinical data for data sharing purpose
Funding and conflicts of interest	7a	Sources of funding and other support (eg, supply of drugs)			
	7b	Financial and other conflicts of interest for principal investigators and steering committee members			
Dissemination policy	8	Plans to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, reporting in trial registry, plain language summary, publication)			
Introduction					
Background and rationale	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	• Prevalence and/or incidence of the condition in the designated trial population • Known variability in prevalence and/or incidence for each included (sub)group • Paediatric (sub)groups who are most affected by the disease or condition
			9a.2†	Describe the potential for extrapolation from other paediatric populations or adult data, or why extrapolation is not considered appropriate	• Whether the disease, interventions, and outcomes in the eligible age groups of children/adolescents are comparable to those in adults or other paediatric populations • From which data extrapolation is done and for what trial-design element extrapolated data are used • If extrapolation is done for the initial dose, method of establishment • Whether extrapolation is being done for efficacy and pharmacokinetic/pharmacodynamics, effectiveness, and/or harms data • Statistical approach to trial modelling and simulation • Reason why extrapolation is or is not considered appropriate

Section/Topic	Item No.	SPIRIT 2025 Statement	Item No.	SPIRIT-Children and Adolescents (SPIRIT-C) 2026 extension	Summary of Key Elements
			9a.3*	Include a description of the research question or aim with a justification for undertaking the trial in children/adolescents	• 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
	9b	Explanation for choice of comparator			
Objectives	10	Specific objectives related to benefits and harms			
Methods: Patient and public involvement, trial design					
Patient and public involvement	11	Details of, or plans for, patient or public involvement in the design, conduct, and reporting of the trial			• Whether children, adolescents, family caregivers (i.e., parents, guardians), family member, and/or adults with relevant lived paediatric experiences will be involved as research partners • Planned level of involvement of children/adolescents, patient or public partners in the design, conduct, reporting, and dissemination of trial results • Expected outcome and impact of children/adolescents and families on trial design, conduct, analysis, reporting and dissemination • Any permissions, research ethics aspects, and privacy considerations related to patient and public involvement
Trial design	12	Description of trial design including type of trial (eg, parallel group, crossover), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)			
Methods: Participants, interventions, and outcomes					
Trial setting	13	Settings (eg, community, hospital) and locations (eg, countries, sites) where the trial will be conducted	13.1†	Describe any adaptations put in place to support inclusion and participation of children/adolescents	• Adaptations, processes, or procedures with respect to trial visit timing, environmental adjustments, data collection, diverse ways to communicate information and address questions, to promote inclusion and retention • How the need for such adaptations was determined, whether with involvement of participants, caregivers, community partners

Section/Topic	Item No.	SPIRIT 2025 Statement	Item No.	SPIRIT-Children and Adolescents (SPIRIT-C) 2026 extension	Summary of Key Elements
					• Whether adaptations need to be considered in the data analysis
Eligibility criteria	14a	Eligibility criteria for participants	14a.1*†	Provide a justification for including multiple age groups or children/adolescents at different developmental stages, and address potential age or development-related differences in treatment effects	• Age groups of eligible participants, and justification on how selected age range(s) enabled the trial to meet its objective • If age groups are not used, applicable developmental stages • Any differences in expected treatment effects and risk-benefit profile accounted for related to age or developmental stage(s) • If any relevant (sub)group is excluded from the trial, include the reason for exclusion
	14b	If applicable, eligibility criteria for sites and for individuals who will deliver the interventions (eg, surgeons, physiotherapists)			
Intervention and comparator	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 (eg, intervention manual) can be accessed			All 12 TIDieR reporting items with corresponding pediatric considerations from TIDieR-C
			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	For both the "experimental" and "comparator" intervention: • How the dose and/or formulation is appropriate for the target population • Provide any available dose/exposure data from paediatric studies or regulatory agencies supporting the choice • Adjustments made to the intervention dose or formulation, based on trial participant's age, weight, or body surface area • Efforts to make the formulation palatable and acceptable for participants, or how this will be assessed • Possible palatability and bio-availability differences between different formulations

Section/Topic	Item No.	SPIRIT 2025 Statement	Item No.	SPIRIT-Children and Adolescents (SPIRIT-C) 2026 extension	Summary of Key Elements
			15a.2†	Give rationale for adapting interventions used in other paediatric populations or adults for the present trial	• Evidence that the original intervention or comparator worked elsewhere with details about the context(s) and populations in which it has been evaluated • The rationale for adapting intervention or comparator to trial population and context with consideration of the intervention-context fit of existing intervention(s) and mapping of similarities and differences between original and new contexts and populations • How adaptations were made, piloted, and evaluated and how the intervention or comparator was implemented, (based on ADAPT), or where this information can be found • Level of confidence on the validity of the adaptations made
			15a.3*†	Describe whether the trial interventions will be delivered with help from a support person	• To what extent assistance is required from a support person and how they will be involved • Who the support person is and if there is any specific training for the support person(s) to deliver the intervention, or to support the participant during intervention delivery • Where appropriate, who will determine the requirement for help, and who will determine who the support person will be • Whether help is required for the intervention only during trial conduct, or also afterwards if intervention is continued post-trial
	15b	Criteria for discontinuing or modifying allocated intervention/comparator for a trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)			
	15c	Strategies to improve adherence to intervention/comparator protocols, if applicable, and any procedures for monitoring adherence (eg, drug tablet return, sessions attended)			
	15d	Concomitant care that is permitted or prohibited during the trial			
Outcomes	16	Primary and secondary outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from			• Pre-specifying the primary and secondary outcomes, including their specific measurement variable, who will

Section/Topic	Item No.	SPIRIT 2025 Statement	Item No.	SPIRIT-Children and Adolescents (SPIRIT-C) 2026 extension	Summary of Key Elements
		baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome			be assessing/gathering the outcome data, time point(s), analysis metric, method of aggregation, and clearly specify if this is the same or different in each prespecified age group • If applicable, whether children, adolescents, or family caregivers will be involved in defining the target difference (e.g., minimal important difference, smallest worthwhile effect), and how they will be involved in defining this difference. If there is an established target difference, include a reference. • Whether a parent or support person will be assessing the primary outcome, and whether any training will be done to facilitate this
			16.1*	Explanation of the validity, reliability, feasibility, and responsiveness of the outcome measurement instruments for the pre-specified age groups	• Justification and relevance of the outcome measurement instrument(s) for the pre-specified 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 are, and whether the outcome measurement instrument(s) are child/adolescent-centred (e.g., if parent-reported outcome, clearly specify if the measure is a parent-proxy report of child outcomes, or a parent self-report)
Harms	17	How harms are defined and will be assessed (eg, systematically, non-systematically)			• If known, whether the foreseen or potential harms including pain or anxiety are reversible or can be treated in children/adolescents • If known, whether the foreseen or potential harms can have lasting impact in children/adolescents • If known, how the harms would be assessed should they occur

Section/Topic	Item No.	SPIRIT 2025 Statement	Item No.	SPIRIT-Children and Adolescents (SPIRIT-C) 2026 extension	Summary of Key Elements
					• What corrective actions would be undertaken for individual participants experiencing harms • How the trial would proceed should harms occur • What preventive and/or mitigating measures can be set into place to minimize expected harms
			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	• Efforts taken to reduce trial intervention-or procedure-related pain and distress in both the experimental and comparator group • Specific strategies that will be used to reduce pain, discomfort, distress, and invasiveness of procedures • If available, evidence on interventions and procedures used to mitigate or treat any potential harms of participation
			17.2	Describe all efforts to reduce the child/adolescent's risk associated with trial participation	• Any foreseen risk associated with participating in the trial • Age-appropriate efforts to reduce this foreseen risk • How children/adolescents and/or parents were involved in planning/deciding on how to reduce harms
Participant timeline	18	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (See Fig 1 in SPIRIT 2025)			
Sample size	19	How sample size was determined, including all assumptions supporting the sample size calculation			
Recruitment	20	Strategies for achieving adequate participant enrolment to reach target sample size			• How recruitment plans may enhance the inclusion of children/adolescents • Infrastructure to support recruitment and retention of children, adolescents, and families • Involvement of trial networks, research consortiums, and cooperatives in recruitment and retention efforts • Engagement with community organisations, schools, and parent groups to raise awareness about the trial and its potential benefits
			20.1	Describe the anticipated impact of trial participation on the child/adolescent's daily life	• Anticipated impact of trial participation on the child and family's daily life • Mitigation strategies that are put in place

Section/Topic	Item No.	SPIRIT 2025 Statement	Item No.	SPIRIT-Children and Adolescents (SPIRIT-C) 2026 extension	Summary of Key Elements
			20.2	Describe how participating children/adolescents will be given recognition for trial participation	• Type of recognition and whether monetary or non-monetary. • If monetary, type of payment based on the ERIC collaborative classification, whether reimbursement, compensation, appreciation, incentives, or a blend. • Rationale of how recognition was decided • Timing of recognition
Methods: Assignment of interventions					
Randomisation:					
Sequence generation	21a	Who will generate the random allocation sequence and the method used			
	21b	Type of randomisation (simple or restricted) and details of any factors for stratification. To reduce predictability of a random sequence, other details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enroll participants or assign interventions			
Allocation concealment mechanism	22	Mechanism used to implement the random allocation sequence (eg, central computer/telephone; sequentially numbered, opaque, sealed containers), describing any steps to conceal the sequence until interventions are assigned			
Implementation	23	Whether the personnel who will enrol and those who will assign participants to the interventions will have access to the random allocation sequence			
Blinding	24a	Who will be blinded after assignment to interventions (eg, participants, care providers, outcome assessors, data analysts)			
	24b	If blinded, how blinding will be achieved and description of the similarity of interventions			
	24c	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial			
Methods: Data collection, management, and analysis					
Data collection methods	25a	Plans for assessment and collection of trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of trial instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be accessed, if not in the protocol			
	25b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols			
Data management	26	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be accessed, if not in the protocol			
Statistical methods	27a	Statistical methods used to compare groups for primary and secondary outcomes, including harms			
	27b	Definition of who will be included in each analysis (eg, all randomised participants), and in which group			
	27c	How missing data will be handled in the analysis			

Section/Topic	Item No.	SPIRIT 2025 Statement	Item No.	SPIRIT-Children and Adolescents (SPIRIT-C) 2026 extension	Summary of Key Elements
	27d	Methods for any additional analyses (eg, subgroup and sensitivity analyses)			
Methods: Monitoring					
Data monitoring committee	28a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and funder; conflicts of interest and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed			
	28b	Explanation of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial			
Trial monitoring	29	Frequency and procedures for monitoring trial conduct. If there is no monitoring, give explanation			
Ethics					
Research ethics approval	30	Plans for seeking research ethics committee/institutional review board approval			
Protocol amendments	31	Plans for communicating important protocol modifications to relevant parties			
Consent or assent	32a	Who will obtain informed consent or assent from potential trial participants or authorised proxies, and how	32a.1†	Provide information on whether developmentally appropriate materials with understandable information on the trial process will be provided to participants in obtaining informed consent or assent, and state where materials can be found or if available on request	• Age group(s) or developmental stage(s) that the trial information material was prepared for • How information and presentation of information will be developmentally appropriate for the target population) • Involvement/engagement of children/adolescents/family caregivers in preparation • Where the developmentally appropriate materials can be found, or whether available on request
	32b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable			
Confidentiality	33	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial			
Ancillary and post-trial care	34	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation			• Whether further care or medication will be available to children or adolescents who complete, are withdrawn or drop out of the study • Any post-trial transitions in care that need to be considered, e.g., from paediatric to adult care

Section/Topic	Item No.	SPIRIT 2025 Statement	Item No.	SPIRIT-Children and Adolescents (SPIRIT-C) 2026 extension	Summary of Key Elements
					• Planned post-trial care and provisions available to children and adolescents, such as how long the care or medication is available for, where they can obtain care, and who will administer care (e.g., parents, healthcare professional)
			34.1†	Describe plans for assessing outcomes and harms beyond the formal study completion date	• Planned outcomes (including harms) that will be assessed, with methods and frequency of assessment • Duration of follow-up past formal trial completion date • How and when results of extended monitoring will be available • If no plans, desired follow-up length to capture important long-term outcomes, and any plans to seek funding for future follow-up or provide a rationale for not needing to conduct long-term follow-up

*New item pertains both to SPIRIT-C 2026 and CONSORT-C 2026[15]; †Report item if applicable; otherwise, state explicitly that it is not applicable

eTable 5. Existing SPIRIT Extensions Relevant to Paediatric Trials*

Topic	Available SPIRIT extensions	Year
Condition	SPIRIT-Path[16] (Cellular and Molecular Pathology Content)	2021
Intervention	TIDieR-C[17] (Paediatric trial interventions)	2025
	SPIRIT-iNeurostim[18] (Implantable neurostimulation devices)	2024
	SPIRIT-TCM[19] (Traditional Chinese Medicine)	2019
	TIDieR[20] (Template for Intervention Description and Replication)	2014
Trial design	SPIRIT-DEFINE[21] (Early Phase Dose-Finding)	2023
	SPIRIT Factorial[22]	2023
	CONSERVE[23] (Modifications due to extenuating circumstances)	2021
	SPIRIT-AI[24] (Artificial Intelligence)	2020
	SPIRIT-SPENT[25] (n-of-1)	2019
Outcomes	SPIRIT-Surrogate[26]	2024
	SPIRIT-Outcomes[13]	2022
	SPIRIT-PRO[27] (Patient Reported Outcomes)	2018

*as of August 2025

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Web Appendix 2: Data Supplement

Data eTable 1. Delphi item flow of candidate SPIRIT-C 2026 items

Item type	Specific/ Relevant	Round 1 Items (n = 32)	Consensus in Round 1*	Round 2 Items (n = 23)	Consensus in Round 2*	Round 3 Items (n = 8)	Consensus in Round 3*
Base	S	Identify that it is a paediatric clinical trial, and include age group(s), interventions, and, if applicable, trial acronym	98% *Consensus reached after R1*	N/A	N/A	N/A	N/A
New / modified	S	Describe, if any, plans of involving patient or public partners, or children's advisory groups, in planning and supporting the dissemination of trial results (e.g., determining timing and frequency of sharing trial results, providing feedback on plain language summaries, co-creating infographics, co-authoring manuscripts, co-presenting results)	59% *Reworded based on feedback, moved onto R2*	Describe, if applicable, any plans to involve, or how patient or public partners (e.g., children, young people, or families), or family/children's advisory groups have been involved in planning and supporting the dissemination of trial results	66% *No consensus after two rounds of voting, to discuss at Consensus Meeting*	N/A	N/A
New / modified	S	Describe how plain language summaries will meet the recommended reading age of Grade 6 (or 11-12 years) for healthcare information (e.g., by using the Simplified Measure of Gobbledygook (SMOG) readability scale)	32% *Reworded based on feedback, moved onto R2*	Describe how plain language summaries will be/have been prepared to be accessible to the trial's participants and their families	18% *No consensus after two rounds of voting, to discuss at Consensus Meeting*	N/A	N/A
New / modified	R	Describe plans for piloting and obtaining feedback on the understandability and appropriateness of the plain language summary with patient and public members	37% *Item removed (E&E)*	N/A	N/A	N/A	N/A
New / modified	S	N/A	N/A	Provide information on whether a child-friendly factsheet with	56%	Provide, if applicable, information on whether a child-	56% *No consensus after two rounds of*

Item type	Specific/ Relevant	Round 1 Items (n = 32)	Consensus in Round 1*	Round 2 Items (n = 23)	Consensus in Round 2*	Round 3 Items (n = 8)	Consensus in Round 3*
[Youth Generated]				understandable information on the trial process (the participant's journey, including the benefits and risks of participation, whether there is a team that can help the child navigate all challenges of trial participation) has been developed and where it can be found	*Reworded based on feedback, moved onto R3*	friendly factsheet with understandable information on the trial process was provided to children in obtaining assent or informed consent, and include where it can be found	*voting, to discuss at Consensus Meeting*
New / modified	S	Scientific background and rationale, including a description of the research question and justification for undertaking the trial in the pre-specified age group, including summary of relevant studies (published and unpublished) or a systematic review examining benefits and harms for each intervention	96% *Reworded based on feedback, moved onto R2*	Include a description of the research question and justification for undertaking the trial in the pre-specified population, cohort, or age group(s)	100% *Consensus reached after R2*	N/A	N/A
New / modified	R	Report race and ethnicity for groups who are most affected by the disease or condition that is being investigated in the trial	53% *Item removed (E&E)*	N/A	N/A	N/A	N/A
New / modified	S	Describe the disease prevalence and/or aetiology of disease and (long term developmental)	76% *Item split into 3, voted on in R2*	Describe, if applicable and known, the prevalence/incidence	71% *Moved onto R3*	Describe, if applicable and known, the prevalence/incidence	82% *Consensus reached after R3*

Item type	Specific/ Relevant	Round 1 Items (n = 32)	Consensus in Round 1*	Round 2 Items (n = 23)	Consensus in Round 2*	Round 3 Items (n = 8)	Consensus in Round 3*
		impact of the disease in children		of the disease or condition in children		of the disease or condition in children	
New / modified	S	N/A	N/A	Describe, if applicable and known, the aetiology of the disease or condition in children	54% *Reworded based on feedback, moved onto R3*	Describe, if applicable and known, the aetiology (cause) of the disease or condition in the paediatric sub-population of interest	29% *No consensus after two rounds of voting, to discuss at Consensus Meeting*
New / modified	S	N/A	N/A	Describe, if applicable and known, the developmental impact of the disease or condition on children	57% *Reworded based on feedback, moved onto R3*	Describe, if applicable and known, the impact of the disease or condition on children	52% *No consensus after two rounds of voting, to discuss at Consensus Meeting*
Base	S	Describe the potential for extrapolation from adult data, or why extrapolation is not considered appropriate and why a trial is considered necessary in the pre-specified age groups	69% *Reworded based on feedback, moved onto R2*	Describe, if appropriate, the potential for extrapolation from other paediatric populations or adult data, or why extrapolation is not considered appropriate	68% *No consensus after two rounds of voting, to discuss at Consensus Meeting*	N/A	N/A
New / modified	S	Describe, if any, the standard of care including definitions, diagnosis, and available treatments	85% *Item removed (redundant)*	N/A	N/A	N/A	N/A
New / modified	R	Describe if the trial was done for regulatory purposes	70% *Reworded based on feedback, moved onto R2*	Describe if the trial was done for regulatory purposes (e.g., seeking marketing	75% *Item removed (E&E)*	N/A	N/A

Item type	Specific/ Relevant	Round 1 Items (n = 32)	Consensus in Round 1*	Round 2 Items (n = 23)	Consensus in Round 2*	Round 3 Items (n = 8)	Consensus in Round 3*
				authorization for a new indication in children			
New / modified	S	If the eligible population crossed childhood developmental stages, provide a justification of the selected age/developmental stage groups, addressing potential age/development-related differences in treatment effects	69% *Reworded based on feedback, moved onto R2*	If multiple age groups or children at multiple developmental stages are eligible to participate, provide a justification for including each and if applicable, address potential age or development-related differences in treatment effects	66% *No consensus after two rounds of voting, to discuss at Consensus Meeting*	N/A	N/A
New / modified	S	Describe whether the trial intervention will affect the child's quality of life (e.g., ability to go to school, vacation, holiday, travel) and if interventions are associated with fear and pain	70% *Reworded based on feedback, moved onto R2*	Describe the anticipated impact of trial participation on the child's daily life (e.g., time off school, social activities)	72% *Consensus reached after R2*	N/A	N/A
New / modified [Youth Generated]	S	N/A	N/A	Describe whether taking the intervention requires help from a parent or caregiver, and if they need to take time off work to help their child	60% *Reworded based on feedback, moved onto R3*	Describe, if applicable, whether taking the intervention as part of the trial requires help from a parent or caregiver	54% *No consensus after two rounds of voting, to discuss at Consensus Meeting*
New / modified	R	After the trial, describe whether the trial intervention will be available and how treatment continuity will	61% *Item removed (redundant)*	N/A	N/A	N/A	N/A

Item type	Specific/ Relevant	Round 1 Items (n = 32)	Consensus in Round 1*	Round 2 Items (n = 23)	Consensus in Round 2*	Round 3 Items (n = 8)	Consensus in Round 3*
		be maintained after the trial					
New / modified	S	Justify, if applicable, either the fixed intervention drug dose or developmental stage-based dose adjustments	87% *Reworded based on feedback, moved onto R2*	Describe, if applicable, 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	94% *Consensus reached after R2*	N/A	N/A
New / modified	S	Describe, if applicable, the availability of an age-appropriate drug formulation	77% *Item merged with above item*	N/A	N/A	N/A	N/A
New / modified	R	If more than one formulation will be used, discuss how quality control measures will be put in place to mitigate any possible differences between the different formulations, and whether the approach is appropriate for the study's medication administration strategy	70% *Item removed (E&E)*	N/A	N/A	N/A	N/A
SPIRIT | CONSORT-Outcomes	R	Provide a rationale for the selection of the domain for	90% *Originally consensus for*	N/A	N/A	N/A	N/A

Item type	Specific/ Relevant	Round 1 Items (n = 32)	Consensus in Round 1*	Round 2 Items (n = 23)	Consensus in Round 2*	Round 3 Items (n = 8)	Consensus in Round 3*
		the trial's primary outcome	*inclusion reached in Round 1, but* *Item removed (E&E)*				
SPIRIT | CONSORT-Outcomes	R	If the analysis metric for the primary outcome represents within-participant change, define and justify the minimal important change in individuals	80% *Originally consensus for inclusion reached in Round 1, but* *Item removed (E&E)*	N/A	N/A	N/A	N/A
SPIRIT | CONSORT-Outcomes	R	If the outcome data collected are continuous, but will be analysed as categorical (method of aggregation), specify the cutoff values to be used	86% *Originally consensus for inclusion reached in Round 1, but* *Item removed (E&E)*	N/A	N/A	N/A	N/A
SPIRIT | CONSORT-Outcomes	R	If outcome assessments will be performed at several time points after randomization, state the time points that will be used for the analysis, and justify the time points used	95% *Originally consensus for inclusion reached in Round 1, but* *Item removed (E&E)*	N/A	N/A	N/A	N/A
SPIRIT | CONSORT-Outcomes	R	If a composite outcome is used, define all individual components of the composite outcome	92% *Originally consensus for inclusion reached in Round 1, but* *Item removed (E&E)*	N/A	N/A	N/A	N/A
SPIRIT | CONSORT-Outcomes	R	Describe who will assess the primary outcome (e.g., nurse, parent)	94% *Originally consensus for inclusion reached in Round 1, but*	N/A	N/A	N/A	N/A

Item type	Specific/ Relevant	Round 1 Items (n = 32)	Consensus in Round 1*	Round 2 Items (n = 23)	Consensus in Round 2*	Round 3 Items (n = 8)	Consensus in Round 3*
			Item removed (E&E)				
SPIRIT | CONSORT-Outcomes	R	Describe what is known about the responsiveness of the study instruments in a population similar to the study sample	72% *Originally consensus for inclusion reached in Round 1, but* *Item removed (E&E)*	N/A	N/A	N/A	N/A
Base	S	Explanation of the validity, feasibility, and responsiveness of the outcome measure instruments for the pre-specified age groups	85% *Consensus reached after R1*	N/A	N/A	N/A	N/A
New / modified	R	Describe the anticipated adverse events and side effects that may occur because of the trial procedures (e.g., pain, impact to participants or family caregivers)	88% *Item merged with item below*	N/A	N/A	N/A	N/A
New / modified	R	N/A	N/A	Describe adverse events and side effects from the trial procedures that may occur or were experienced Note: Originally only CONSORT-C item in R1, made into a SPIRIT-C Item R2 onwards after modification from comments in R1	98% *Item removed (E&E)*	N/A	N/A

Item type	Specific/ Relevant	Round 1 Items (n = 32)	Consensus in Round 1*	Round 2 Items (n = 23)	Consensus in Round 2*	Round 3 Items (n = 8)	Consensus in Round 3*
New / modified	S	Describe the efforts to reduce the child's risk of participation including ways to reduce distress, i.e., pain, anxiety, fear to children	77% *Reworded based on feedback, moved onto R2*	Describe, if applicable, whether trial interventions and/or procedures are associated with fear, pain, distress, or are invasive, and what measures are taken to reduce potential harms of participation	88% *Consensus reached after R2*	N/A	N/A
New / modified [Youth Generated]	R	N/A	N/A	Describe whether occurring adverse events can be treated	62% *Item removed (E&E)*	N/A	N/A
SPIRIT | CONSORT-Outcomes	R	Define and justify the target difference between treatment groups (e.g., the minimal important difference)	94% *Originally consensus for inclusion reached in Round 1, but Item removed (E&E)*	N/A	N/A	N/A	N/A
New / modified	S	N/A	N/A	Describe, if applicable, research partners (e.g., patients, caregivers, healthcare providers) involved in defining the target difference (e.g., minimal important difference, smallest worthwhile effect) Note: Originally only CONSORT-C item in R1, made into a SPIRIT-C Item R2 onwards after	42% *Item removed (E&E)*	N/A	N/A

Item type	Specific/ Relevant	Round 1 Items (n = 32)	Consensus in Round 1*	Round 2 Items (n = 23)	Consensus in Round 2*	Round 3 Items (n = 8)	Consensus in Round 3*
				modification from comments in R1			
SPIRIT | CONSORT-Outcomes	R	Describe any planned methods to account for multiplicity in the analysis or interpretation of the primary and secondary outcomes (e.g., coprimary outcomes, same outcome assessed at multiple time points, or subgroup analyses of an outcome)	87% *Originally consensus for inclusion reached in Round 1, but Item removed (E&E)*	N/A	N/A	N/A	N/A
Base	S	Describe all efforts to reduce the child's risk of participation	77% *Consensus reached after R1*	N/A	N/A	N/A	N/A
New / modified	R	Describe how data integrity, protocol deviations/violations, and subject withdrawals will be assessed and handled	86% *Moved onto R2*	Describe how data integrity, protocol deviations/violations, and subject withdrawals will be assessed and handled	94% *Item removed (E&E)*	N/A	N/A
Base	R	Describe plans for assessing outcomes and harms beyond the formal study completion date	62% *Moved onto R2*	Describe plans for assessing outcomes and harms beyond the formal study completion date	49% *No consensus after two rounds of voting, to discuss at Consensus Meeting*	N/A	N/A
New / modified [Youth Generated]	S	N/A	N/A	Describe whether participants are offered payment (appreciation, compensation,	75% *Reworded based on feedback, moved onto R3*	Describe how participating children or youth will be recognized for trial participation (e.g.,	88% *Consensus reached after R3*

Item type	Specific/ Relevant	Round 1 Items (n = 32)	Consensus in Round 1*	Round 2 Items (n = 23)	Consensus in Round 2*	Round 3 Items (n = 8)	Consensus in Round 3*
				incentives, and reimbursement) related to trial participation		appreciation, compensation, incentives, reimbursement)	
New / modified [Panellist suggested]	S	N/A	N/A	Describe any accommodations (e.g., communication aids, environmental adjustments) to support children's participation and inclusion	64% *Reworded based on feedback, moved onto R3*	Describe, if applicable, any adaptations put in place to support inclusion and participation of children (e.g., communication aids, environmental adjustments)	61% *No consensus after two rounds of voting, to discuss at Consensus Meeting*
New / modified [Panellist suggested]	S	N/A	N/A	Describe, if applicable, any experiences and outcomes collected from trial participant's parents or guardians	49% *Item removed (redundant)*	N/A	N/A
Base	S	Describe plans, if any, for post-trial care beyond the paediatric age range	50% *Item removed (redundant)*	N/A	N/A	N/A	N/A
New / modified [Youth Generated]	S	N/A	N/A	Describe what information is shared with others (e.g., researchers, parents), and how the privacy of the child and/or family is being treated within the study	76% *Reworded based on feedback, moved onto R3*	Describe if individual participant data will be shared with others not directly involved in the trial (e.g., other researchers, clinicians, parents), and how the child and/or family's confidentiality of the	85% *Consensus reached after R3*

Item type	Specific/ Relevant	Round 1 Items (n = 32)	Consensus in Round 1*	Round 2 Items (n = 23)	Consensus in Round 2*	Round 3 Items (n = 8)	Consensus in Round 3*
						will be respected within the study	

Note: Numbering for items is not included as it changed throughout the project.
*Defined as percentage of Delphi panellists who voted the item as a score of 7-9 (critical for inclusion) for “New/modified items” or “Yes, keep” for “Base” or “SPIRIT | CONSORT-Outcomes” items

Data eTable 2. Consensus meeting results for SPIRIT-C 2026 relevant items that were voted on

Item	Voting Results n (%)*	Consensus status	Core team decision
Describe, if applicable and known, the aetiology (cause) of the disease or condition in the paediatric sub-population of interest	Include: 4 (13%) Exclude: 26 (87%) Total voters: 30	Consensus out	N/A
Describe, if applicable and known, the impact of the disease or condition on children	Include: 14 (47%) Exclude: 16 (53%) Total voters: 30	No consensus	Include in E&E as detail
Describe, if appropriate, the potential for extrapolation from other paediatric populations or adult data, or why extrapolation is not considered appropriate	Include: 23 (77%) Exclude: 7 (23%) Total voters: 30	Consensus in	N/A
Describe, if applicable, any plans to involve, or how patient or public partners (e.g., children, young people, or families), or family/children's advisory groups have been involved in planning and supporting the dissemination of trial results	Include: 8 (26%) Exclude: 22 (71%) Abstain: 1 (3%) Total voters: 31	Consensus out	N/A
Describe how plain language summaries will be/have been prepared to be accessible to the trial's participants and their families	Include: 6 (19%) Exclude: 25 (81%) Total voters: 30	Consensus out	N/A
Provide, if applicable, information on whether a child-friendly factsheet with understandable information on the trial process was provided to children in obtaining informed consent, and state where it can be found or if available on request	Include: 24 (77%) Exclude: 6 (19%) Abstain: 1 (3%) Total voters: 31	Consensus in	N/A
If multiple age groups or children at multiple developmental stages are eligible to participate, provide a justification for including each and if applicable, address potential age or development-related differences in treatment effects	Include: 27 (90%) Exclude: 3 (10%) Total voters: 30	Consensus in	N/A
Describe, if applicable, whether taking the intervention as part of the trial requires help from a parent or caregiver	Include: 20 (65%) Exclude: 11 (35%) Total voters: 31	No consensus	Include
Describe, if applicable, any adaptations put in place (e.g., communication aids, environmental adjustments) to support inclusion and participation of children	Include: 23 (74%) Exclude: 8 (26%) Total voters: 31	Consensus in	N/A
Describe plans for assessing outcomes and harms beyond the formal study completion date	Include: 19 (61%) Exclude: 12 (39%) Total voters: 31	No consensus	Include
If applicable, give rationale for adapting interventions used in other paediatric populations or adults for the present trial (for specific guidance see ADAPT guidance)**	Include: 24 (77%) Exclude: 6 (19%) Abstain: 1 (3%) Total voters: 31	Consensus in	Include

Note 1: Numbering for items is not included as it changed throughout the project.
Note 2: "Consensus in" means that the item met consensus criteria to be included. "Consensus out" means that the item met consensus criteria to be excluded.

* Max voting members at the meeting (n = 31); however, there is variability in the total voters across items as some panellists did not vote before we had to move on. For items that reached no consensus, two rounds of voting took place; results depicted are of the second vote.
**Item was not originally a SPIRIT-C 2026 item going into the Consensus Meeting, but was deemed appropriate to be a SPIRIT-C 2026 item during the meeting and was voted “in”

Data eTable 3. Item wording evolution after the Consensus Meeting

Final item #	E&E writing/review	Pilot testing	Final wording
1a.1	Identify that it is a paediatric clinical trial, and include age group(s), interventions, and if applicable, trial acronym	Identify that it is a paediatric clinical trial, and include age group(s), interventions, and if applicable, trial acronym	Identify that it is a paediatric trial protocol, and include age group(s)/ranges, interventions, and, if applicable, trial acronym
6.1	Describe if individual participant data will be shared with others not directly involved in the trial (e.g., other researchers, clinicians, parents), and how the child and/or family's confidentiality will be respected within the study	Describe whether individual participant data will be shared with other not directly involved in the trial (e.g., other researchers, clinicians, parents), and how the child/adolescent's and/or family's confidentiality will be respected within the study	Describe whether individual participant data will be shared with others not directly involved in the trial, and how the child/adolescent's and/or family's confidentiality will be respected within the study
9a.1	Describe, if applicable and known, the prevalence/incidence of the disease or condition in children	Describe the prevalence/incidence of the disease or condition in children/adolescents	Describe the prevalence/incidence of the disease or condition in children/adolescents
9a.2	Describe, if appropriate, the potential for extrapolation from other paediatric populations or adult data, or why extrapolation is not considered appropriate	Describe, if appropriate, the potential for extrapolation from other paediatric populations or adult data, or why extrapolation is not considered appropriate	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 and justification for undertaking the trial in the pre-specified population, cohort, or age group(s)	Include a description of the research question and justification for undertaking the trial in the pre-specified population or age group(s)	Include a description of the research question or aim with a justification for undertaking the trial in children/adolescents
13.1	Describe, if applicable, any adaptations put in place to support inclusion and participation of children (e.g., communication aids, environmental adjustments)	Describe, if applicable, any adaptations put in place to support inclusion and participation of children/adolescents	Describe any adaptations put in place to support inclusion and participation of children/adolescents
14a.1	Provide, if applicable, a justification for including multiple age groups or children at different developmental stages, and address potential age or development-related differences in treatment effects	Provide, if applicable, a justification for including multiple age groups or children/adolescents at different developmental stages, and address potential age or development-related differences in treatment effects	Provide a justification for including multiple age groups or children/adolescents at different developmental stages, and address potential age or development-related differences in treatment effects
15a.1	Describe, if applicable, whether there is an intervention dose and/or formulation	Describe whether there is an intervention dose and/or, if applicable, formulation appropriate for	Describe whether there is an intervention dose and/or formulation appropriate for the trial

Final item #	E&E writing/review	Pilot testing	Final wording
	appropriate for the trial population, and if there are any adjustments made based on age, weight, or body surface area	the trial population, and if there are any adjustments made based on age, weight, or body surface area	population, and if there are any adjustments made based on age, weight, or body surface area
15a.2	If applicable, give rationale for adapting interventions used in other paediatric populations or adults for the present trial (for specific guidance see ADAPT guidance)	If applicable, give rationale for adapting interventions used in other paediatric populations or adults for the present trial	Give rationale for adapting interventions used in other paediatric populations or adults for the present trial
15a.3	Describe, if applicable, whether taking the intervention as part of the trial requires help from a support person	Describe, if applicable, whether taking the intervention as part of the trial requires help from a support person	Describe whether the trial interventions will be delivered with help from a support person
16.1	Explanation of the validity, feasibility, and responsiveness of the outcome measure instruments for the pre-specified age groups	Explanation of the validity, feasibility, and responsiveness of outcome measure instruments for the pre-specified age groups	Explanation of the validity, reliability, feasibility, and responsiveness of the outcome measurement instruments for the pre-specified age groups
17.1	Describe, if applicable, whether trial interventions and/or procedures are associated with fear, pain, distress, or are invasive, and what measures are taken to reduce potential harms of participation	Describe, if applicable, whether trial interventions and/or procedures are associated with fear, pain, distress, or are invasive, and what measures are taken to reduce potential harms of participation	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's risk of participation	Describe all efforts to reduce the child/adolescent's risk of participation	Describe all efforts to reduce the child/adolescent's risk associated with trial participation
20.1	Describe the anticipated impact of trial participation on the child's daily life (e.g., time off school, social activities)	Describe the anticipated impact of trial participation on the child/adolescent's daily life	Describe the anticipated impact of trial participation on the child/adolescent's daily life
20.2	Describe how participating children or youth will be recognized for trial participation (e.g., appreciation, compensation, incentives, reimbursement)	Describe how participating children/adolescents will be recognized for trial participation	Describe how participating children/adolescents will be given recognition for trial participation
32a.1	Provide, if applicable, information on whether developmentally appropriate materials with understandable information on the trial process was	Provide, if applicable, information on whether developmentally appropriate materials with understandable information on the trial process will be provided to participants in obtaining	Provide information on whether developmentally appropriate materials with understandable information on the trial process will be provided to participants in obtaining

Final item #	E&E writing/review	Pilot testing	Final wording
	provided to participants in obtaining informed consent or assent, and state where it can be found or if available on request	informed consent or assent, and state where materials can be found or if available on request	informed consent or assent, and state where materials can be found or if available on request
34.1	Describe, if applicable, plans for assessing outcomes and harms beyond the formal study completion date	Describe, if applicable, plans for assessing outcomes and harms beyond the formal study completion date	Describe plans for assessing outcomes and harms beyond the formal study completion date

*Item wording changed slightly during drafting of Statement and E&E papers.

Note 1: Between the E&E writing/review and pilot testing phase, we edited the phrasing “children” to “children/adolescents” to align with the scope of the guidelines.

Note 2: Between the pilot testing and final wording, we removed all instances of “if applicable”, and these items are labelled with a dagger in the final checklist to indicate that it should only be reported if applicable.

Note 3: For items with further elaborations in brackets, these were removed from the main item and the detail included in the explanation text of the E&E instead.

Note 4: Other than the global changes applied in Note 1, 2, and 3, items with wording evolutions from pilot testing feedback are in the green boxes. Items with wording changes based on feedback from the editorial process are in a pink box.