Development of Reporting Guidelines for Child Health Trials

SPIRIT | CONSORT
CHILDREN
Reporting Guidelines for Child Health Trials

2024 Q2 Newsletter

Greetings from Toronto! We hope this newsletter finds you well. We are at an exciting point of the development of SPIRIT | CONSORT-Children and would like to inform you about progress and upcoming project phases. Please consider this a two-way street: we are happy to hear from you if you would like to share your thoughts or ideas, or if this newsletter raises any questions.

- The Core Project Team: Ami Baba, Maureen Smith, Beth Potter, An-Wen Chan, David Moher, and Martin Offringa

Productive Youth and Family Caregiver Input

Young Person Reporting Guideline Workshops: In December 2023 and January 2024, five Young Persons Reporting Guideline Workshops were conducted in Canada, England, France, Scotland, and Spain. Attendees shared what information they think should be reported in paediatric trial protocols and reports. Young people in these workshops identified five (5) new “candidate reporting items” for voting in the Delphi study. A total of **42 youth** (ages 10-21 years) attended these workshops:

Canada
- Seven youth ages 12-19 years
- Youth are members of various Young Persons Advisory Groups (YPAGs), such as KidsCAN, INFORM RARE Youth Avisory Group, SickKids Patient Advisors

France
- Seven youth ages 12-17 years
- Youth are members of the Kids France YPAG

England
- Ten youth ages 12-21 years
- Youth are members of the GenerationR YPAG

Scotland
- Eight youth ages 12-17 years
- Youth are members of the ScotCRN YPAG

Spain
- Ten youth ages 10-21 years
- Youth are members of the Kids Barcelona YPAG

Two Advisory Groups: The Canadian team includes a group of six youth advisors (ages 13-19 years) and five family caregiver advisors, who are involved throughout the project (e.g., advising on youth workshop materials, design of the Delphi study) and contributing to various project activities.

In October 2023, we onboarded youth from across Canada who either have lived experience of being a trial participant, who read trial results to inform their own healthcare decision making, and/or those who have experience partnering with researchers to the **Youth Advisory Group (YAG)**. They provided advice on (materials for) the international Young Person Reporting Guideline Workshops, and on how best to share this project’s findings with other youth. The final YAG meeting will take place in May 2024, where they will advise on knowledge translation strategies to youth, and reflect on their involvement in this project.

Similarly, we onboarded five parents in Canada into the **Family Caregiver Advisory Group (FCAG)**. Parents in the FCAG either have children that participate(d) in a clinical trial, or who read trial results to inform healthcare decision making for their child’s health condition. FCAG has been involved throughout the project and has advised on the design of the Delphi study, piloted Rounds 1 and 2 of the Delphi, and took part as Delphi panelists. Interested members also have the opportunity to join the **June 2024 Consensus Meeting** and co-author the **Explanation and Elaboration (E&E) documents**.

Delphi Study News

Our consensus-based method to select a minimum set of indispensable trial reporting items involved a three-round Delphi study that took off in January 2024 and concluded on May 1, 2024. Candidate reporting items generated by youth in the workshops were voted on in Round 2 and 3. Numerous international pediatric/child health clinical trial stakeholders were involved in this global initiative, including four young people (ages 19-24) and 10 family caregivers (e.g., parents, guardians).

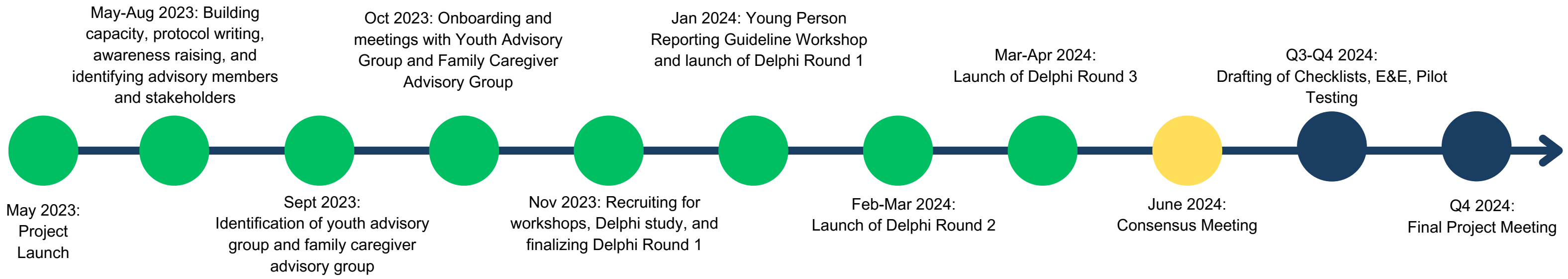
Thanks to the input from all panelists, we made significant process towards reaching consensus on a minimum set of items for an essential, useful, and harmonized guidance. Over 170 panelists from 30 countries completed Round 1, while over 140 panelists who completed Round 1 completed Round 2. Over 90% of those who have completed Round 2 have completed the final round. Amazing panelist engagement and contributions!

We will be holding a special **post-Delphi debrief** with panelists who have identified as young persons (ages 19-24) and family caregivers to give them an opportunity to reflect on their experience in being a Delphi panelist. Shared learnings and reflections will be compiled for a publication to add to the growing literature of patient and public involvement (PPI) in methodological research.

Upcoming project phases

We look forward to the next phases of the project. On the horizon, a formal **Consensus Meeting** will be held virtually in June 2024 to “lock” the **Checklists** with reporting items to be included into the final SPIRIT | CONSORT-C.

Shortly after the consensus meeting, we will assemble a writing team to write and review the **Explanation and Elaboration (E&E) documents**. Once the drafts of both the checklist and E&E are ready, we will launch the pilot testing in Q3 2024. The **Final Project Meeting** will be dedicated to review drafts of all final deliverables, to be published in international peer reviewed Journals.



May 2023: Project Launch

May-Aug 2023: Building capacity, protocol writing, awareness raising, and identifying advisory members and stakeholders

Sept 2023: Identification of youth advisory group and family caregiver advisory group

Oct 2023: Onboarding and meetings with Youth Advisory Group and Family Caregiver Advisory Group

Nov 2023: Recruiting for workshops, Delphi study, and finalizing Delphi Round 1

Jan 2024: Young Person Reporting Guideline Workshop and launch of Delphi Round 1

Feb-Mar 2024: Launch of Delphi Round 2

Mar-Apr 2024: Launch of Delphi Round 3

June 2024: Consensus Meeting

Q3-Q4 2024: Drafting of Checklists, E&E, Pilot Testing

Q4 2024: Final Project Meeting

Publications to date

Read more about the project in recently published articles:

Viewpoint:
https://pubmed.ncbi.nlm.nih.gov/38147343

Protocol:
https://pubmed.ncbi.nlm.nih.gov/38287439

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