

Development of Reporting Guidelines for Child Health Trials

2023 Fall Newsletter

Dear SPIRIT/CONSORT-Children International Advisory Group (IAG),

Greetings from Toronto! We hope this newsletter finds you well. As we near the end of 2023, we'd like to share project updates to date, and inform you about upcoming phases of the project. Please consider this a two-way street: we are very happy to hear from you if this newsletter raises any questions or concerns, or if you would like to share your thoughts or ideas in our upcoming IAG meeting. We hope you enjoy reading this newsletter!

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

Youth Involvement

Earlier this summer, we met with the eYPAGnet group based in Europe to consult them on how to involve youth in the SPIRIT/CONSORT-C project. We also had a consultation with the KidsCan Young Person Advisory Group (YPAG) for their thoughts on how youth can help make the SPIRIT/CONSORT-C project successful, what would make them want to be in the project, and what would help youth get involved.

We have since formed the *Youth Involvement International Steering Committee*, consisting of members of the eYPAGnet group (Jennifer Preston, Begonya Nafria, Segolene Gaillard, Pamela Dicks) and members of the SPIRIT/CONSORT-C team (Maureen Smith (Patient Partner Lead), Ami Baba, and Martin Offringa), to come up with a plan on how to meaningfully involve youth in the SPIRIT/CONSORT-Children project. Through discussions, we landed on involving youth internationally using a “hub-and-spoke” model.

At a glance: Youth Advisory Group

The **Youth Advisory Group (YAG)** consists of six youth (ages 13-19) 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. They are involved throughout the project, advising us on YPRG Workshop materials, and in knowledge translation of the findings to other youth.

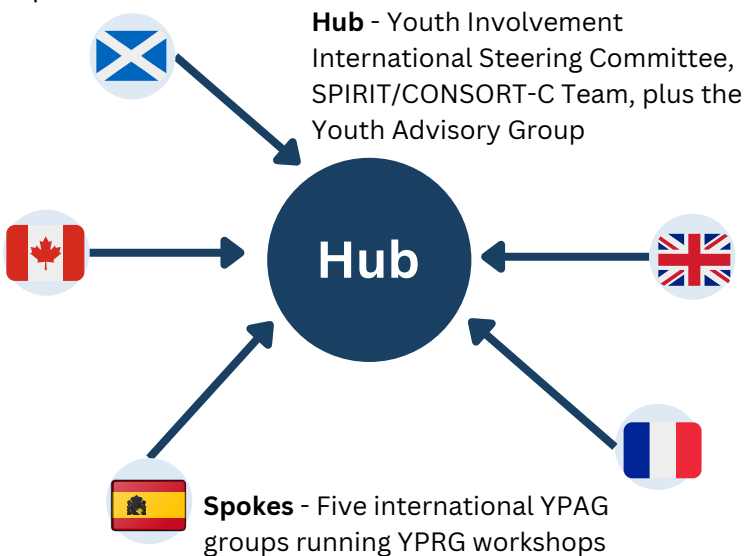
Fortunately, most of the advisory group members have indicated their interest in joining the YPRG workshops themselves in January 2024 as contributors to generate items for SPIRIT/CONSORT-C.

Progress update: In October 2023, we met with the YAG to onboard them and to consult them on materials for the YPRG workshops.

The “hub” consists of the SPIRIT/CONSORT-C team in Canada, the Youth Involvement International Steering Committee members, and the Youth Advisory Group based in Canada. The hub has designed the upcoming Young Person Reporting Guideline Workshops and materials that will be used.

The “spoke” consists of five Young Person Advisory Groups (YPAG) based in the United Kingdom (Liverpool, Scotland), France, Spain, and Canada. Concurrent to the launch of Delphi Round 1, these YPAG groups of at least 10 youth will run Young Person Reporting Guideline (YPRG) workshops with young people ages 12-22 to come up with potential items for inclusion in the SPIRIT/CONSORT-C guidelines.

The YPRG workshops will yield important items to be reported from the youth directly. These “youth candidate” items will be voted on during Delphi Round 2 by Delphi panelists. The generation of these items by youth is vital as they are among the ultimate end-users of what is reported in trial protocols and reports.



Family Caregiver Involvement

In addition to youth involvement, we formed a Family Caregiver Advisory Group (FCAG) based in Canada. The FCAG consists of five parents who 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. They will be involved throughout the entire project, and will help us design and pilot the Delphi study, take part as Delphi panelists, co-lead the consensus meeting, co-author the Explanation and Elaboration (E&E), and help with knowledge translation initiatives. In addition to the five FCAG parents, we will involve 10 additional family caregivers to take part in the Delphi study as panelists. The family caregiver input is critical as they are among the direct end-users of the published trial protocols and reports, and their opinion on what is relevant to report, and how to report it is important.

Progress Update: In October 2023, we met with the FCAG to onboard them and get advice on making the Delphi training session and the Delphi survey understandable to family caregivers. Prior to the launch of Delphi Round 1, we will hold a Delphi Training Session in January 2024 with all family caregivers to get them ready for the Delphi study.

Delphi Study

We put together a “candidate item” list for Delphi Round 1 that are *specific* or *relevant* to all child health/pediatric clinical trials. We reviewed items in the upcoming SPIRIT/CONSORT 2023 checklists and items from the “base checklist” - these are items from the initial development effort that reached consensus at the time, and were informed by two systematic reviews in 2015. We also conducted an environmental scan of the literature to identify any new potential items. We reviewed all existing SPIRIT/CONSORT extensions as of July 2023. The current “candidate item” list comprises of a combination of all identified items; these will be voted on during Delphi Round 1. During Delphi Round 1, we will invite panelists to vote on items for inclusion or exclusion, but will also offer the opportunity to suggest new items. These new items will be incorporated in Delphi Round 2, along with the items generated by youth during the Young Person Reporting Guideline Workshops

Progress Update: In November 2023, we focus our efforts on refining the final list of items for the Delphi, piloting the first round, and finalizing the Round 1 survey. We will hold an International Advisory Group meeting to discuss the scope, and seek your help in sending out the Delphi Registration Form to all those who may be interested in contributing.

Delphi Round 1 will launch the week of January 8, 2024. Round 2 will launch in February 2024, and the final round in March/April 2024.

We need your help!

Please think of any colleagues or networks who would be interested in contributing to the Delphi! We aim for at least 150 international child health trial researchers to complete the three Delphi rounds. Ami will send the Delphi registration form by e-mail in November 2023. Please send them the Delphi registration form, or let Ami know who to contact so we can get them signed up for the Delphi.

Project timeline and overview of the next 6 months

