

Introduction

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ABBREVIATIONS

SDG—standard development group

StaR—Standards for Research in

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Much has been written regarding the paucity and shortcomings of pediatric clinical trials, largely stemming from particular methodological and practical challenges of conducting research in children. In an effort to improve and expand the evidence-base for child health, a new initiative called Standards for Research in (StaR) Child Health was founded in 2009. The initiative involves an international group of researchers, methodologists, practitioners, regulators, and journal editors who seek to develop practical and evidence-based guidance to enhance the reliability and relevance of pediatric clinical research.

It was determined that the goals of StaR Child Health could best be met through the development of “standard development groups” (SDGs), which comprises an international group of experts in a given field. These groups would systematically work to address each of StaR Child Health’s identified priorities.

In the first article of this supplement, the StaR Child Health agenda and rationale is introduced. To date, 6 SDGs have been assembled to address the issues of the following: consent and recruitment; containing risk of bias; data monitoring committees; determining adequate sample sizes; the selection, measurement, and reporting of outcomes; and appropriate age groups for pediatric trials. The recommendations of these groups are provided in the guidance articles that follow in this series. The SDGs assembled and exchanged information to optimize pediatric trial methodology by means of correspondence, regular teleconferences, and occasional meetings. In their discussions, the SDG members tried to reach consensus. However, they agreed that there will always be differences of opinion and that as long as there is no evidence, there is not a single “gold standard” approach.

Editing of this series has been completed by Drs Terry Klassen, Jonathan Craig, Kristy Wittmeier, and Martin Offringa. Manuscripts were reviewed and edited by this group, in consultation with one another as well as the original authors of each manuscript. The final version of each manuscript was approved by the authors and editors.

This supplement addresses 6 of the priority issues identified by StaR Child Health so far. Future SDGs will address the remaining priorities, as well as newly identified issues concerning pediatric research quality and conduct.

The mission of StaR Child Health is to improve the quality of the design, conduct, and reporting of pediatric clinical research by promoting the use of modern research standards. For more information about StaR Child Health, or to find out how you may become involved, visit our Web site at www.starchildhealth.org.

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