SECTION 1: GETTING STARTED

Contents

How to Use these Resources

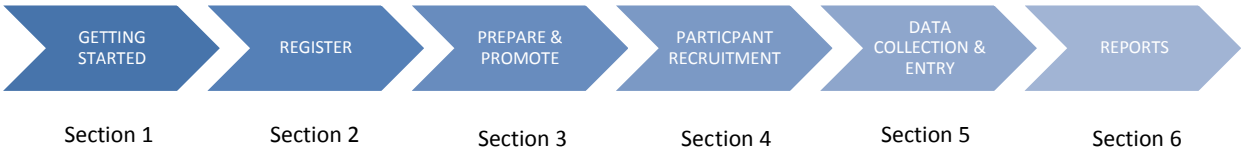
Purpose

The purpose of the study resources is to facilitate consistency in the implementation of the EFFORT Trial across participating ICUs. It is a 'cookbook' that transforms the study protocol into procedures related to trial organization, operation, site registration, participant screening, recruitment, enrollment, data collection methods, data flow, case report forms (CRFs) and quality.

Organization

Study resources are organized into sections for ease of use. Each section will explain activities that need to be completed by the sites before progressing to the next section. Also, included are resources like document templates and tools that the sites may adapt for local use.

Figure 1: Organization of Study Materials



Study Resources

Each section has associated resources that the participating site may download for use. The use of these tools and document templates is strongly suggested however, it is left to the discretion of each participating site to determine whether the document templates and/or tools should be revised to adhere with local practice and policy.

When reading through the study procedures, any document templates or tools associated with specific content will be noted with the icon.

Tools provided in MS Excel (.xls or .xlsx) format, will include an 'Instructions' tab that will explain how the tool is recommended to be used. Some of these tools are meant to be used a running logs or lists; others are calculators that can be used to make data collection easier.

Documents and tools provided in MS Word (.doc or .docx) format are arranged to have any instructions highlighted and *italicized*. These instructions can be deleted from the template before the site adopts it for use.

Other tools may be MS PowerPoint (.ppt or .pptx) slides or simply links to online resources.

If you have any suggestions for tools or resources that are not currently found please contact the Central Project Leader (see contact details below).

Contacts & Communications

Principal Investigators

Dr. Daren Heyland
Email: dkh2@queensu.ca
Mobile: +1-403-915-5573

Charlene Compher
Email: compherc@nursing.upenn.edu
Office: +1-215-898-3619

American Society for Parenteral and Enteral Nutrition (ASPEN) Representatives

Charlene Compher
Email: compherc@nursing.upenn.edu

Todd Rice
Email: todd.rice@venderbilt.edu

Nilesh Mehta
Email: Nilesh.Mehta@childrens.harvard.edu

Jayshil Patel
Email: jpatel2@mcw.edu

Coordinating Centre

Central coordination of the trial is being conducted by the Clinical Evaluation Research Unit (CERU) located in Kingston, Ontario, Canada. Visit www.ceru.ca for more information.

Central Project Leader

Janet Overvelde
Email: mailto:Janet.Overvelde@kingstonhsc.ca Office: +1-613-549-6666 ext. 6241

Project Assistant (Spanish Speaking Lead)

Luis Ortiz
Email: laor@queensu.ca Office: +1-613-549-6666 ext. 4146

National Coordinators

A National Coordinator for The EFFORT Trial will be chosen in each country/region from among the participating sites. This National Coordinator will be the national contact person for the study and have the responsibility of communicating with the network of participating sites in his/her country/region. In addition, he/she may lead the national or central ethics application in their country/region, if applicable.

Refer to National Coordinators List on the website for the most current contact details.

Authorship Policy

All participating ICUs will be acknowledged in the 'Acknowledgement section' of the primary manuscript emerging from the EFFORT trial. The participating institution as well as the names of the two study leads will be noted in the acknowledgement.

Authorship policy is set by journals and generally states that coauthors must have contributed to the 2 or more of the following tasks:

1) Design of the protocol;
2) Collection of data;
3) Analysis and interpretation;
4) Preparation and critical review of the manuscript.

As an incentive and to acknowledge the top enrolling sites, we plan to offer 'authorship' to the top 3-4 enrolling sites provided that they assist with the write up phase of the paper. It is generally understood that members of the EFFORT Steering Committee and Data Monitoring Committee will also be acknowledged. Dr. Heyland, Compher and Rice will be the leading authors of the manuscript and others from the Steering Committee and top enrolling sites as well will be included, as explained above. This trial has been formally endorsed and supported by the American Society of Enteral and Parental Nutrition and as such, ASPEN will also be acknowledged in any future publications.