



Guidelines for ELSO Registry Addenda Development and Revision

Addendum Development Group Standing Committee Members

- ELSO Addendum Development Group Co-Chairs
- Addendum Development Group Members-at-Large
- Current or Past Registry Database Development Co-Chairs
- Current or Past ELSO Registry Chair
- ELSO CEO or Executive Director

Background: The ELSO registry is designed to be a comprehensive database for the compilation of international outcomes in patients who require Extracorporeal Life Support (ECLS) encompassing a variety of diverse patient populations. The ELSO Registry, while comprehensive, may not necessarily collect specific details of interest to all clinicians regarding individual patient populations and/or ECLS indications (Cardiac, ECPR, etc.). In order to provide this level of detail where indicated, the ELSO Registry Database Development Committee and its Sub-Committee: The Addenda Development Group (ADG), has developed guidelines for both the de-novo creation and/or subsequent revision ELSO Registry Addenda. This supplemental information is designed to augment, not replace, the existing registry information thus providing greater detail in a variety of patient populations and/or ECLS indications.

The following guidelines are intended for ELSO members who wish to create any new data collection addenda for the ELSO registry or request a revision to an existing addendum. Guidelines were developed by the ELSO ADG to standardize the process for inquiries regarding ELSO database addenda creation or revision. The ELSO ADG is a voluntary committee comprised of international experts in ECLS without any conflicts of interest. The role of the ADG is to aid the development of any proposed addenda and serve at the behest of the ELSO Registry Chair and ELSO Steering Committee.

Minimum Criteria: The following are minimum criteria for all new and revised existing addenda and should be kept in mind prior to and during the initiation and development of any addenda:

- It must be clearly demonstrated that any new addendum would fulfill a need within the ECLS community not currently provided by the main registry. Any revised addenda must clearly demonstrate a lack of fulfilment of the current need which that existing addenda should be providing.
- A minimum of ~40 ELSO Member Centers must support the proposed addendum or revision.
 - Each investigator should provide a list of the ECLS Director and name of the center that has agreed to support this addendum creation along with signed commitment letter (attached).
 - Currently there are approximately 400 centers contributing to the ELSO Registry.
- The development of any new addendum or alterations to an existing addendum have projected costs typically ranging from \$5,000-\$15,000 US Dollars.
 - Investigators are responsible for agreeing on a fee prior to building the addenda and each is responsible for obtaining his/her own funding for addenda creation/revision. Final pricing will be contingent upon discussion with registry developer.
- Creation of a separate database definition manual is required to ensure reliability of validity of data entry.
 - Each investigator is referred to the ELSO Database webpage for examples of existing database definitions

Initial Inquiry: Prior to the initiation of any new addendum development or alterations of exiting addendum, answers to the following questions should be submitted in writing to the ADG Committee:

- New addendum
 - What addendum do you want to create and why?
 - What is the specific indication (disease process, ECLS indication, ancillary technique/technology) you are trying to detail?
 - What do you hope to gain by the addition of this addendum?
 - What is the estimated prevalence of this indication in the ECLS community?
 - What is the estimated prevalence in the existing ELSO registry? If low, Is this a rapidly growing population in the ELSO database?
 - Is the proposed addendum applicable to all age groups?
- Revision of exiting addendum
 - What existing database addendum do you wish to revise and why?
 - What do you hope to gain with alterations to the existing addendum?
 - Are the proposed addendum alterations applicable to all age groups?

**Once reviewed, you will be contacted directly by a member of the ADG with a disposition and next steps. No projects should begin until given approval by the ELSO ADG and verification of the minimum requirements confirmed.

Addendum Development: Once the above criteria have been met and the project meets with the approval of the ADG, the investigator should establish an Addendum Development Work Group. This should include members of the ADG and a discrete number of multidisciplinary experts, familiar with the subject matter. These experts should adequately represent the target audience globally and provide feedback on the proposed project.

Once the Addendum Work Group is convened, the following processes should occur:

- A process of justification which should include some review of the literature regarding the proposed addendum topic for relevant factors that would be important to collect.
- Audit the existing ELSO registry and existing addenda for relevance and data points
- Construct or rebuild in line with current clinical practice and best available evidence
 - Add missing data elements from the current ELSO data collection
 - Explain the need for additional data collection points
- Work group provides targeted expert opinion to optimize data elements
- On-going teleconferences for revision of existing data fields and proposed new fields with the following in mind:
 - Need for reformatting of the evolving collection tool optimizing to a core dataset
 - Avoid repetition of data points already collected in the main ELSO registry
 - Simple answers (yes/ no), only.
 - User friendly format similar format as existing ELSO database addendums
 - Elements classified as Mandatory or Non-Mandatory in keeping with the style of the revised ELSO Registry Database Definitions
 - Length should be kept to minimum necessary to avoid data entry fatigue
 - Consider applicability to the broadest range of patient age groups (neonates/pediatric/adults)

Once complete, the addendum work group should expect to Conduct external peer review by submission to a broader range of experts for critique and revision. The addendum will then undergo a similar process from above prior to final consideration.

The proposed addenda and all supporting document will be submitted for final consideration to the ELSO Steering Committee for final approval. Once approved, investigators are encouraged to submit their addenda and development process for publication in peer reviewed publications where appropriate. Novel Addenda and/or Revised Addenda developers and committees will have right of first refusal to a prespecified number of publications pertaining to each addendum. This will be agreed upon prior to release of the data.

Expected time frame for development and presentation for build should 12 to 18 months. Examples of previous addenda and their supporting documentation can be provided at the investigators request.

The continued utility of each addenda will be reviewed by the ADG every 3-5 years. The ADG, the registry Development Committee, and therefore ELSO reserves the right to discontinue the use of any addenda which does not continue to contribute meaningfully to its mission.

Questions or concerns please contact the ADG.