Extracorporeal Life Support Organization

Registry Data: Access, Requests, and Publication Policy

OVERVIEW

The purpose of the ELSO Registry ("Registry") is to provide ELSO members with data to improve the quality of care to patients (centers, industry, researchers). Data submitted by Centers to the Registry includes personally identifiable information: gender, race, nature, and severity of illness, technical details of extracorporeal support used, dates of service, complications, and outcomes. All collected data is listed in the ELSO ECLS registry forms and addendums completed by Centers when they submit data.

Only de-identified data is released. ELSO provides several ways for centers to view their data relative to the ELSO Registry, including quality assurance reports, a quality dashboard, and views of a center's data for certain metrics. Centers can query the Registry, as needed, for support in clinical decision-making, for institutional quality assurance, benchmarking, and clinical research according to procedures described in this policy. The codes or computations enabling identification are not released. ELSO may allow queries to the Registry of de-identified data by regulatory bodies and industry to advance the care and safety of patients requiring Extra-Corporeal Life Support. Approval by the Scientific Oversight Committee is required for all requests. All Registry data is stored in a secure server environment with enhanced cyber security protocols in place.

DATA

- All data submitted to the ELSO Registry contains no patient identifiers except for what is allowed under ELSO's Data Use and Transfer Agreement.
- The Center ID that connects the data to the providing Center is used only for quality assurance reports submitted to the Center.

ACCESS

- Registry data is only available to active participating Centers. An active Center registers at least one patient (neonatal, pediatric, or adult) per quarter. A Center not registering a patient for 12 consecutive months will be queried. A Center registering no patient for 18 consecutive months will be considered inactive.
- Only Centers whose ELSO dues are paid in full will be considered active. Data requests from Centers with more than six months in arrears will not be honored.
- A signed Data Use Agreement (DUA) must be on file before any data requests will be granted. A DUA is required when a center joins ELSO.
- Data is only given to requestors other than the depositing Center either in aggregate form or without the Centers' names or identifiers.
- Special requests from persons or organizations that are not part of an ELSO Center (NIH, industry, etc.), will be considered by the Scientific Oversight Committee.

REQUESTS

- Data Request forms for publication and internal use can be found on the ELSO website.
- Requests that involve joining external datasets to the ELSO registry data will only be possible with financial compensation for the work involved. Specific charges will be determined by the scope of work. As of January 1, 2022, there will be a minimal expected fee of $18,500. Please contact the ELSO office for details. Email to ELSODataRequest@elso.org.
- Data requests from a Center must be submitted and signed by either the ECMO Director or the ECMO Coordinator of the Center.
- New requests for data will be limited to one outstanding and one new request per principal investigator. An outstanding request has not been submitted as an abstract to a scientific conference or a manuscript to a scientific journal.

- The Scientific Oversight Committee (SOC) does not disclose the submitting Center's name in conjunction with data provided by that Center. Some research studies may benefit from analyses accounting for clustering of patients from the same Centers. These requests will be adjudicated by the SOC as required, and if approved, an anonymized Center identifier will be provided (policy available on the ELSO website). Requests for data deemed politically charged will not be honored.
- Requests for data to be used for publication will be reviewed with previous data request submissions to ensure there is no substantial overlap. The date/time of request establishes the priority of the request. Data is only to be released to one investigator at a time for a particular study question. In cases where an overlap is found with existing approved studies, both investigators will be contacted to determine if substantial overlap exists. Final discretion for data release is the decision of the ELSO Registry chair(s).
- ELSO Registry will release large datasets to investigators for purposes of important research. The release will be based on the impact of the intended research. However special rules regarding handling, use, and reporting of these data will be enforced. Please see the ELSO Large Data Set request policy found on the ELSO website.
- Datasets from the ELSO Registry are released after a study proposal has been submitted for Data Request review and approved by the SOC. Released data should only be used to test the hypotheses included in the study proposal. Any further analysis of the dataset needs to be resubmitted for review to ensure the data has not been released to other investigators. This process is essential to the integrity of the ELSO Registry data and is respectful of the resources and effort expended by other investigators.
- Any additional data required for analysis must be requested with the Data Request form. Additional data requests will be reviewed by the Registry or SOC Chair(s) to determine whether the additional data is a significant enough change to be presented at a full Data Request Review Committee Meeting.
- Data cannot be shared or distributed to anyone besides those listed in the submitted data request form and can only be used for the sole purposes outlined in the request.
- ELSO does not release manufacturer information and does not allow investigators to identify individual manufacturers, products, or centers in their publications or reports.
- ELSO does not release dates other than the year of ECMO run, only time intervals.
- Approved data requests will be published on the ELSO website including date of data delivery and expected date of completion. The purpose of publishing this list is to allow researchers the ability to view current ongoing projects in order to avoid overlapping requests.

PUBLICATION

- Only one published manuscript per data request is allowed.
- Investigators are allowed 12 months of exclusive access to the data for the questions articulated in the proposal, with the following caveats. Some proposals have broad questions that cover entire populations, groups, or concepts. In these cases, we may release specific subpopulations or data for specific narrow questions in situations where this does not explicitly overlap with the stated aims of the investigators. Example: Investigator 1 receives data on "outcomes from VA ECMO in adults" and has not specifically specified analysis of patients with pre-existing renal failure. Investigator 2 may be released data <12 months later, focusing on "the outcomes of adult VA ECMO patients who were supported on RRT before ECMO." At 12 months, we will notify the investigators that data may be released to other waiting investigators. Both old and new investigators will be notified that data is out to two groups. ELSO may in cases of failed progress in a reasonable period, notify the investigators that they have a 3-6 month window to finish their analysis, at which point ELSO reserves the right to tell the investigators that they can no longer publish on the data. This is to ensure that delayed publications don't come out that encroach on newer investigators approved for data before they completed analysis.
- Special circumstances: for COVID-19 related data, investigators have only 3 months of exclusive access to the data.
- Data requests for projects intended for publication are reviewed once a month by the SOC. Once approval is granted the data request will be honored.
- Investigators are invited to submit a copy of the abstract or manuscript to the SOC to ensure the accuracy of data analysis and conclusions when using registry data. After publication, investigators are required to provide a copy of the manuscript to ELSO for purposes of monitoring the use and publication of ELSO Registry data. The SOC may request a manuscript review prior to submission. The purpose of the manuscript review is to: 1. Ensure that the report does not identify/expose centers, 2. Check that the proposed hypothesis was tested, and 3. Check that the research team stayed within the bounds which were documented with acceptance of the proposal (if any).

- Large data requests which are approved are required ELSO Registry scientific oversight committee approval of the manuscript prior to submission for publication. Investigators should factor this requirement into their proposed timeline.

DATA VIOLATIONS

- Data use violations are defined as the use of ELSO Registry datasets to explore analyses that were not proposed as part of Data Request. Publications from data use violations will result in consequences for the investigators and the center director. Initial examples of consequences include – an initial warning, but if repeated infringements occur, the investigators and center director may be refused access to ELSO Registry data for 12-24 months which will be communicated as part of the data use violations notification.
- Any data use violations may result in a Letter of Correspondence to the journal or editor from the Extracorporeal Life Support Organization. This letter will be in the public domain.

Acknowledgment of ELSO Registry in Publications

Any publication based on Registry data must acknowledge the ELSO Registry as the data source. The Registry face sheet can be published with acknowledgment only and does not require prior approval. Publication of more detailed Registry data requires approval by the ELSO Registry Large Data Set Committee. Local IRB approval is not required to be provided to ELSO when only de-identified data is requested; however, the requester should be familiar with his or her institution's IRB policies. Data requests for publication that are a duplication of an earlier request by another investigator may be honored at the discretion of the ELSO Registry Scientific Oversight Committee. In these cases, attempts to contact the earlier investigators or arrange collaboration will be made.

All academic products resulting from an investigation of ELSO Registry data must include reference to 'the ELSO Registry'. Publications in the scientific literature should reference the ELSO Registry as 'the ELSO Registry' or the Extracorporeal Life Support Organization Registry' in the published abstract.

The ELSO Registry should be cited as:
ECMO Registry of the Extracorporeal Life Support Organization (ELSO), Ann Arbor, Michigan, (Month), (Year).