

EXTRACORPOREAL LIFE SUPPORT ORGANIZATION



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Device Developer Data Policy

The Extracorporeal Life Support Organization (ELSO) Registry

The Extracorporeal Life Support Organization (ELSO) Registry is a database of international extracorporeal membrane oxygenation (ECMO) use submitted voluntarily by ELSO member centers. There are over 400 active centers submitting over 10,000 cases to the ELSO Registry annually. The Registry includes detailed information on patients, devices, health outcomes and associated health complications. This data is valuable for research, device evaluation, identification of devices or services used, and support for approval by regulatory bodies. ELSO believes the extracorporeal community of patients, health care providers, and hospitals are served by sharing ELSO data with partners who strive to bring new devices and services to future patients relying on extracorporeal care.

The ELSO Registry continually strives to improve data accuracy. Data is entered per [detailed instructions for data entry](#). Accuracy is assessed in real-time at the point of data entry by warning data enterers if data is suspect and rejecting outlier data. The ELSO Registry administers a voluntary data entry exam to all data enterers (mandatory as of 2019). ELSO maintains audit trails of all persons entering data and any changes made to data.

Vision for Partnership between the ELSO Registry, Device Developers, and Regulatory Bodies.

The 21st Century Cures Act, 2016 directed regulatory bodies to use *real world evidence* to support regulatory decision making. The US Congress characterized *real world evidence* as data regarding the use, benefits and risks, of a drug using sources *other than clinical trials*. [Food & Drug Administration \(FDA\) clarified sources of real world data](#) to be electronic health records, **product and disease registries**, claims and billing activities, patient-generated data, data gathered from mobile devices.

ELSO Corporate membership is a prerequisite to access to ELSO Registry data by device developers to assist in advancing extracorporeal life support technologies. As in all releases of ELSO Registry data, ELSO will steward the data in a manner that protects patient and center data confidentiality. In addition, ELSO will not release data for marketing purposes and ELSO does not allow the use of Registry data for identification of competitors or for advertising. Patient level ELSO data will not be released. Instead, ELSO will analyze the data as requested and release the analysis or aggregate data. Please see below for more detail.

An ELSO Corporate Member can request data on that company's specific devices. The data presentation and analysis can be tailored to the Corporate Member's interests. For example, data can be stratified by ECMO support type, age group, geographic location or diagnostic categories. The data analysis can include

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comparison of a specific device to a group of similar devices in the Registry (but not other specific devices from a single different device developer).

1. Data in the Standard Registry Reports.

The Standard Registry Reports are available to ELSO Corporate Members who have paid the annual ELSO corporate dues. The complete worldwide data in the Registry is reported every six months to center, corporate, and individual members. The ELSO Registry reports summarizes worldwide and ELSO Chapter specific trends in ECMO utilization and median ELSO center volumes. ELSO Chapters include: North America, Europe, Latin America, South West Asia and Africa as well as Asia Pacific ELSO. The reports also summarize survival rates, complication rates, and ECMO run duration. These results are reported overall and stratified by age group, support type, and primary disease category.

Examples:

How many neonatal cases are done each year?

What is the incidence of oxygenator or pump failure, and what is the impact on outcome?

2. Data in the Registry used by industry for submission to regulatory agency including re-labelling.

Re-labelling existing devices for prolonged use.

The Circulatory Support Devices Branch at the FDA, communicated willingness to evaluate ELSO Registry data to support claims for re-labelling of devices for prolonged use. This applies to devices already approved for six-hour use. Analysis will be performed by a doctoral biostatistician retained by ELSO who is experienced in analyzing ELSO data. The ELSO Registry will supply the analyzed aggregate data but will not release patient level data. ELSO can also supply a third party written report of the analysis.

Total Fees: Fees will be the sum of the itemized fees below.

1. *Data request fee:* Contact ELSO for pricing.
2. *Effort-dependent fee(s):* ELSO will also charge the fee of an ELSO contracted statistician. This fee will be estimated ahead of time by based on the requestor's written proposal for analysis. If a report is requested a fee for this service will also be included in the proposal.

3. Data not in the Registry requiring additional data from the ELSO centers.

Data for Supporting 510K Applications for Devices Considered to be Equivalent to Devices Currently in the Registry.

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The ELSO Registry can be supplemented with additional new data describing clinical use of a new equivalent device that is not currently collected in the ELSO Registry to support 510K applications for FDA approval of equivalent devices.

Informed consent and permission to use and analyze the new device data will need to be obtained from each individual center where new the device is being tested. Data submitted to the Registry will be de-identified. The company can compare the new device to existing data in the Registry about predicate devices. For example, study data on a new adult oxygenator can be compared to performance data on all adult oxygenators in the Registry meeting similar criteria. Data on a specific device as predicate from the Registry could be used. ELSO can be contracted to assist with data collection, statistical analysis, and study design for evaluation of new devices.

Steps to undertake this process.

- A. The requestor will prepare a proposed addendum form for additional data collection. See example: <https://www.else.org/Registry/DataDefinitions,Forms,Instructions.aspx>
- B. The requestor will be responsible for developing a database definitions manual that includes the following fields for every item.
 - 1) **Field Name** is the name of the variable as it appears in the online document in the above link.
 - 2) **Definition/ Explanation/ Example** provides the definition of the variable with an explanation of the how to collect the variable and when appropriate an example of choosing the correct data collection
 - 3) **Data Entry Rules** refers to formatting rules for data entry and any warnings or restrictions on data entry. For example, you will receive a **Soft Notification** or warning when entering data that falls outside common values or if that value could represent a more common entry in a different unit. The warning does not mean data has been incorrectly it is just an opportunity for you to double check your data entry. The data enter will receive a **Hard Limit** when data is restricted from entry. This means ELSO assesses the value to be incorrect. For example, we do not allow the entry of ECLS Start Time after the Date of Death.
 - 4) **Collection / Modification** describes the dates the data has been collected and if there was a modification of the variable collected when that modification occurred.
 - 5) **Column Name / Stored Values** describes the column or variable name and stored values for a given variable. For example, the data field "**Hand Bag Valve Ventilation**" is stored in the column (under the variable name) "**HandBagging**" and is stored with values "**0 = No**" "**1 = Yes**" "**-1= Unknown.**"
 - 6) See <https://www.else.org/Registry/DataDefinitions,Forms,Instructions.aspx>
- C. ELSO's web application provider and the data requestor will review the data fields and discuss how the module should appear on completion.

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- D. Prior to building the addendum the requestor will need to identify if there are center characteristics (such as volume or population served) that will be a requirement for centers to participate in data collection. ELSO will also facilitate testing of data collection to gauge the effort and time will be required to collect the data.
- E. The requestor can ask for direct delivery of this data or for delivery of analyzed data performed by an ELSO contracted statistician.

Total Fees: Fees will be the sum of the itemized fees below

- 1. *Data request fee:* Contact ELSO for pricing.
- 2. *Effort-dependent fee(s):*
 - a. ELSO will charge a per patient fee for collection of data that will be specific to the data collection requested.
 - b. ELSO's web application provider will charge a fee to build the web application specific to the module requested.
 - c. If the requestor would like ELSO to analyze the data, ELSO will also charge the fee of an ELSO contracted statistician. This fee will be estimated ahead of time by based on the requestor's written proposal for analysis.

ELSO will not release data that puts center identity or patient identity at risk. All communication regarding data collection and dispersal will be through ELSO. Given that this process represents a new mechanism for ELSO that is aimed at collecting new information ELSO anticipates that there will be some adjustments that need to be made through the process as a ELSO delivers a new service.