

INDEPENDENT AUDITOR'S ASSURANCE REPORT

To the management of the European Congenital Heart Surgeons Association:

This report is intended solely for the management of European Congenital Heart Surgeons Association (hereinafter "the ECHSA") for the purpose of reporting on a statement made by the ECHSA's management, that ECHSA collects, stores, and processes for scientific purposes, anonymized data complying with GDPR requirements.

The assurance engagement relates to the following statement made by ECHSA's management.

Statement made by ECHSA's management

ECHSA maintains a Congenital Database which collects, stores, and processes for scientific purposes, completely anonymized data of surgical procedures submitted by each participating Center, complying with GDPR requirements.

Specific Purpose

This report is intended solely for the purposes specified in the first paragraph above and for your information and must not be used for other needs or distributed to other recipients. The report refers exclusively to the statement made by ECHSA's management and must not be associated with any ECHSA statements as a whole.

Responsible Party's Responsibilities

ECHSA Management is responsible for internal controls being designed and implemented to prevent the anonymized data of surgical procedures submitted by each participating Center from being materially misstated.

In addition, ECHSA Management is responsible for ensuring that the documentation provided to the auditors is complete and accurate. ECHSA Management is also responsible for maintaining the internal control system that reasonably ensures that the documentation described above is free from material misstatements, whether due to fraud or error.

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Auditor's Responsibilities

We conducted our assurance engagement in accordance with International Assurance Standards, particularly ISAE 3000 (revised). These regulations require that we comply with ethical standards and plan and perform our assurance engagement to obtain reasonable assurance about the anonymity of the data maintained for scientific purposes in ECHSA's Congenital Database, relating to the surgical procedures submitted to the Database by each participating Center.

We apply International Standard on Quality Control 1 (ISQC 1), and accordingly, we maintain a robust system of quality control, including policies and procedures documenting compliance with relevant ethical and professional standards and requirements in law or regulation.

We comply with the independence and other ethical requirements of the IESBA Code of Ethics for Professional Accountants, which establishes the fundamental principles of integrity, objectivity, professional competence and due care, confidentiality and professional behavior.

The procedures selected depend on the auditor's judgment. The procedures include, in particular, inquiry of the personnel responsible for monitoring the ECHSA's Database reporting and risk management and additional procedures aimed at obtaining evidence about the ECHSA's Management statement.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our conclusion.

In respect of the statement mentioned above we have performed procedures such as the Center data export to obtain evidence for compliance with GDPR requirements.

Auditor's conclusion

In line with GDPR compliance requirements each participating Center submits data regarding the surgical outcome or procedures in an anonymised manner. The ECHSA Congenital Database does retain the anonymity of the subjects, and as such no patient identification data is uploaded to the Database.

Based on the procedures performed and evidence obtained, the ECHSA's Management statement that the ECHSA Congenital Database, which collects, stores, and processes for scientific purposes, completely anonymized data of surgical procedures submitted by each participating Center, complying with GDPR requirements, is, in all material respects, fairly stated.

Athens, April 26, 2022
The Certified Auditor Accountant

A handwritten signature in blue ink, appearing to read 'A. Androutsopoulos'.

Aristotelis Androutsopoulos
SOEL Registration Number 23271

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