

Rules of Procedure

for the Data Use and Access Committee (DUAC) of the AKTIN Emergency Department Data Registry

Disclaimer: This document is an English translation of the Rules of Procedure for the AKTIN Emergency Department Data (ED) Registries Data Use and Access Committee, provided for the convenience of non-German speaking users. Please note that this translation is intended for informational purposes only and may not capture every detail or nuance of the original German text. It is not legally binding. For all legal and formal purposes, the original German version of the document should be referred to as the authoritative source.

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Preamble

The AKTIN Emergency Department Data Registry can collect continuous and cross-institutional data in clinical emergency medicine. This promises to improve medical care for the estimated more than 21 million emergency patients per year through healthcare research, quality assurance measures, and health surveillance. The basis of the Emergency Department Data Registry is the data set developed by the Emergency Documentation Section of the German Interdisciplinary Association for Intensive Care and Emergency Medicine (DIVI) for standardized and structured documentation in the emergency department, from which the registry data set was defined. The dataset can be viewed at:

<https://art-decor.org/ad/#/aktin-/scenarios/scenarios/2.16.840.1.113883.2.6.60.3.4.33/2019-12-05T08:17:05>.

A decentralized IT infrastructure implemented in the participating hospitals ensures that the data remains in the individual hospitals and thus in the treatment context. If an inquiry is made for a scientific question, only the necessary anonymized data will be merged in compliance with data protection.

To ensure the scientific quality of the data requests to the registry and the data evaluations, a Data Use and Access Committee (DUAC) is elected in accordance with §15 of the statutes of the AKTIN e.V. association, which evaluates the data requests and ensures the ethical and data protection compliant use of the registry data. In the following, according to AKTIN e.V. Statutes §15 para. 5, the work of the DUAC (tasks, rights, and obligations, as well as the organizational structure) is determined.

§1 Tasks

The DUAC conducts an in-depth assessment of the research requests before they are forwarded to the participating sites and a data query is carried out there. In doing so, the DUAC examines the following points:

- Scientificity
- Clinical relevance
- Ethics
- Privacy

Publications containing data from the registry must be submitted to the DUAC (see §5).

§ 2 Composition and Appointment

The composition and appointment of the members of the DUAC is regulated in the statutes of the association AKTIN e.V. under §15 sentences 1 – 5.

The DUAC is made up of 8 people entitled to vote:

- a. Four representatives of the participating emergency departments
- b. One independent epidemiologist or biometrician
- c. 1. Chairperson of the Executive Board (right of veto)
- d. IT Director/CIO of the Executive Board (veto right)
- e. Data protection officer (veto right)

It is possible to appoint representatives for the voting members of groups a and b. The veto right of groups c, d, and e is limited to situations of personal liability. If a representative of groups c, d, and e exercises his right of veto, this must be justified and the possibility of remedying the critical content must be granted.

§3 Procedural Regulation on Applications for Data Evaluation from the AKTIN Emergency Department Data Registry to the DUAC

Applications for data evaluation from the AKTIN Emergency Department Data Registry can be submitted to the DUAC by medical and scientific staff of participating hospitals and contractually defined cooperation partners. There are no costs for these applicants.

Medical and scientific staff from other institutions (professional societies, universities, (university) hospitals, colleges and non-economic research institutions) are also entitled to submit applications for data evaluation. The processing of the application and the provision of the results is subject to a fee for the groups of persons not mentioned in §3 para. 1 (see Annex 1 Fee Schedule).

Before writing the application, it is strongly recommended to contact the office of the Emergency Department Data Registry and to seek advice from the administrative and scientific

registry coordinators. In formulating the application, the scientists are supported by a list of variables in the registry data set, among other things.

The content of the application for data evaluation will be reviewed by the DUAC and, if necessary, adjusted in consultation with the scientist. With the submission of the application, the researcher receives a ticket number (Emergency Department Data Registry project ID). This project ID is mandatory for any information about the processing status and finally for the retrieval of the results. In addition, a unique query ID is generated. Query ID and Emergency Department Data Registry project ID are sent to the technical coordinator (IT support) of the Emergency Department Data Registry (query ID to collect the query results, Emergency Department Data Registry project ID for communication with the requester). The research request (with query ID) is then programmed and sent to the participating institutions.

Processing of a request for data evaluation

1. Documentation and formal review of the application by the AKTIN Office
 - Date of receipt
 - Enquirer with contact details
 - Type of planned publication or other exploitation
 - Eligibility to apply (and fee collection)
 - Study registration (e.g. DRKS)
 - Compliance with the publication regulations
2. Forwarding the application to the Trusted Data Analytics Centre (TDAC) for pre-screening and evaluation of
 - Availability
 - Variables
 - Feasibility in principle
3. Forwarding of the pre-screened application to the DUAC for consideration of
 - Scientificity
 - Clinical relevance
 - Ethics
 - Privacy
4. Holding a meeting of the DUAC (monthly, virtual) to discuss and decide on requests for data analysis. The applicants are invited to the presentation of their applications, the presentation should not exceed 5 minutes, then 10 minutes can be discussed. The decision on the application will take place in camera/ excluding the applicants.
5. Written documentation of the individual opinions of the DUAC by the administrative coordinator of the Emergency Department Data Registry
 - Participants
 - Individual votes
 - Overall vote
6. Transmission of the overall vote to the DUAC and the scientific coordinator of the Emergency Department Data Registry for release

7. If the vote is positive, the application and the vote will be forwarded to AKTIN IT and the query will be implemented.
8. In the event of a negative vote, the vote will be forwarded to the applicant, if necessary with references to the requested revision.
9. After revision of the application, it can be submitted again to the Emergency Department Data Registry, stating the Emergency Department Data Registry project ID with the note of the resubmission.

§4 Procedure for the Review of Publications from Registry Data

The publication regulations of the Emergency Department Data Registry (Annex 2) apply to the publication of evaluations of the registry data. The review of a publication is carried out by the scientific coordinator of the Emergency Department Data Registry.

§5 Communication Matrix

1. All communication is primarily conducted via an e-mail distribution list. Regular face-to-face meetings of the DUAC are not planned. Applications received are usually sent to the DUAC by e-mail on a monthly basis. Decisions are made in monthly web conferences. If no applications have been received, no meeting of the DUAC will take place.
2. In justified exceptional cases (e.g. urgency of the evaluation, special circumstances), a decision on applications is also possible in the shortened e-mail circulation procedure. A member of the executive board of AKTIN e.V. decides on the existence of a justified exceptional case.
3. The coordination of the DUAC's work and the documentation of requests are carried out by the administrative coordinator of the Emergency Department Data Registry.

§6 Passing of resolutions

Decisions of the DUAC on the acceptance or rejection of a request for data evaluation require a simple majority of the members of the DUAC present. At least 4 members of the DUAC must be present at the deliberations.

§7 Amendments to the Rules of Procedure

Changes to the rules of procedure require the approval of the AKTIN e.V. board (absolute majority).