

Terms and Conditions for the use of anonymised pooled data by Non-Participants for statistics and research purposes

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1. Definitions

Non-participants are individuals or groups of individuals from academic institutions

- 1) who have never contributed data to the international Spine Tango registry, or
- 2) who have contributed data to the international Spine Tango registry in the past, but have ceased their contribution.

The anonymised pooled data of the Spine Tango registry includes all clinical data that was submitted to the Spine Tango registry and are owned by EUROSPINE. No patient-identifiable personal data are included in this pooled data.

Spine Tango Task Force (STTF) is the board that steers the further development of the registry and that reviews and approves requests for accessing the anonymized pooled data of the registry for quality assurance and research purposes.

NEC Software Solutions is the provider of IT, statistical and reporting services for EUROSPINE.

2. Terms and conditions

- 1) The study must be approved by the STTF based on the study protocol. The criteria for the study approval are
 - a. The study protocol is scientifically and methodologically sound;
 - b. The use of the EUROSPINE data is justified and the study is scientifically valuable;
 - c. The analysis of the EUROSPINE data is feasible;
 - d. The use of the EUROSPINE data is not posing ethical risk and protection of patients' rights can be guaranteed.
- 2) No patient-identifiable personal data may be released;
- 3) Hospital-identifiable data may only be released upon prior consent of the hospital;
- 4) Patient-level data without patient-identifiable personal data may be released if the planned study justifies and requires this. In each such case, a data use agreement is required;
- 5) If patient-level data are not released, NEC Software Solutions will extract and analyse the data as specified in the study protocol on behalf of EUROSPINE;
- 6) Authorship shall be determined based on [ICMJE authorship guidelines](#);

- 7) For a research study (unless only epidemiological data or information is requested like general frequencies or similar) at least top-3 centres that have contributed the most cases to the studied patient population shall be invited (via Spine Tango team) to participate in the related study with an intellectual contribution;
- 8) EUROSPINE and NEC Software Solutions have to be mentioned in the publication using the following or a similar text: *“The data has been extracted and analysed by NEC Software Solutions on behalf of EUROSPINE. It represents activity recorded in the international Spine Tango registry. This data is made available for use under the agreement between all parties.”*;
- 9) For a research study (unless only epidemiological data or information is requested like general frequencies or similar), all centres that contributed cases to the studied patient population shall be listed in the acknowledgement. The list of the centers will be provided by EUROSPINE;
- 10) In order to control the effort, the number of such Non-Participants studies will initially be limited to 10 per year.
- 11) If several study requests are submitted and EUROSPINE resources need to be prioritised, urgent applications will be given priority if any and if the urgency is justified, otherwise the application submitted first will be considered;
- 12) EUROSPINE recommends publication of the analyses of EUROSPINE data in EUROSPINE’s journal “Brain and Spine”. There is, however, no obligation to do so.

3. Fees components and rates

Service	Fee component	Fee in EUR incl. VAT
Communication and management	Fixed fee	200
Assessment of the request	Fixed fee	250
Extraction of the required data	Fixed fee	250
Analysis	Variable fee	100 EUR per hour