

Spine Atlas Initiative FAQ

Version 0.3; September 2024

Table of Contents

Introduction	1
What is the Spine Atlas Initiative?	1
What is the goal of the initiative?.....	1
What is the specific aim of the data call 2025?	1
General information	1
Who can participate in the Spine Atlas Initiative?	1
How is SAI organised, steered, and funded?	1
Who is part of the SAI steering committee?	2
Who can I contact in case of questions?	2
Benefits for participants.....	2
Overarching benefits	2
What are benefits of the data submission for hospitals?	3
What are benefits of the data submission for registries?	3
The initiative supports and follows the further development in the harmonization of the data structures within registries.	3
How can I participate?	3
Estimated efforts to share data:	3
How will data be submitted?	3
When will I need to submit my data?	3
When will the results be presented?.....	4
Data Analysis and publication	4
How will the data be combined and analysed?.....	4
How is the representativeness of the data submitted handled?	4
The data will be reported by country if deemed representative of the related country. The SAI steering committee will decide for each country if the coverage and representativeness of the data are sufficient to produce comparable single-country statistics for them. The steering committee will use the metadata survey answers from each participant to aid that decision. For details see section 11.5 in protocol	4
When and where will the data be published?.....	4
What will be the authorship?	4
GDPR compliance and Data protection	5
How is compliance with the General Data Protection Regulation (GDPR) and other rules warranted?	5
Do participants need to apply to their local ethics committee?	5
Should patients be informed and does the participating individual or institution need to obtain and document patient’s consent?	5
Will the participating individual or institution have to confirm that informed patient consent has been obtained?	6
Will patient-identifiable data be allowed, processed, or used in the Spine Atlas Initiative?	6
Will hospital-level data be disclosed in the study?	6
Will the collected and pooled data be used for another purpose than the Spine Atlas Initiative?	6
Will patient-identifiable personal data be collected or released?	6
Can hospital-identifiable data be released?	6
Can patient-level data without patient-identifiable personal data be used?	6

What data will be collected in the Spine Atlas data set?	6
How will the Spine Atlas Data retention and data security be ensured?	7
How long will the Spine Atlas Data be retained?	7
Additional FAQ for Spine Atlas participants collecting data using Spine Tango.....	7
Are there additional General Terms & Conditions for using Spine Tango?	7
Is there a template Spine Tango Patient Informed Consent document available?	7
Where can I find the Spine Tango FAQ on data protection and information security?	7

Introduction

What is the Spine Atlas Initiative?

Inspired by international cancer registration, Spine Atlas is an international epidemiological initiative aiming to visualise spine services and practice variations in spinal care across geographical boundaries.

What is the goal of the initiative?

The goal of the initiative is to have a working mode and an approach for running epidemiological studies across borders with the help of spinal registries and to test the availability and practicability of the use of a core dataset in epidemiological studies as well as to collect and combine data on spinal pathologies and treatments from different countries.

What is the specific aim of the data call 2025?

The data call 2025 is dedicated to the epidemiology of lumbar degenerative spondylolisthesis (LDS). The initiative aims to collect 8 mandatory and 7 optional key data parameters for surgically treated lumbar degenerative spondylolisthesis from each participating country for a duration of three months. The aims are the description of spinal surgery infrastructures and practice variation in spinal care for LDS.

General information

Who can participate in the Spine Atlas Initiative?

- An individual surgeon/ health care provider
- An individual hospital, institution, or department
- An established registry
- A Spine Tango hospital

How is SAI organised, steered, and funded?

The SAI team is funded and based at EUROSPINE. It consists of Christian Herrmann (PI), Emin Aghayev (steering committee), Sandy Sutter and Sylvia Hartog.

The SAI team will organise and administrate the initiative. Statistical analyses will be led by Christian Herrmann.

The data collection efforts require primarily personnel resources. They will have to be provided by the individual hospitals and/or established registries.

The data evaluation, presentation to the hospitals, and publication will be covered by the available Spine Tango's budget of EUROSPINE.

Who is part of the SAI steering committee?

- **Christian Herrmann**, PhD MSc (PI)
EUROSPINE, the Spine Society of Europe
- **Pierre Côté**, PhD (Epidemiology, Methodology)
Professor Ontario Tech University Research Excellence
Director, Institute for Disability and Rehabilitation Research, Ontario, Canada
- **Jarkko Halme**, MD (Spine registries)
Orthopaedic spinal surgeon at the Kuopion yliopistollinen sairaala KYS, Kyopio, Finland
Representative of the International Spine Registries working group
Board member of the Finnish Spine Registry (FinSpine)
Chair elect of the European Spine Society Advisory Board (EuSSAB)
- **Emin Aghayev**, MD MSc (Spine registries)
Head Research Development at Research Campus of the Lindenhof Hospital Group, Switzerland
Senior Advisor Spine Tango at EUROSPINE
Project Manager of the Swiss Spine Implant Registry SIRIS
- **Florian Ringel**, PhD MD (Neurosurgery)
Director of the Department of Neurosurgery, University Medical Centre Mainz Representative
from the European Association of Neurosurgical Societies (EANS)
Chairman of the EANS Spine Section
President elect of the German Spine Society
- **Sabrina Donzelli**, MD MSc (Clinical research)
Research Director National Scoliosis Center, Fairfax, Virginia, US
Chair of the Spine Tango Committee
President of the International Society on Scoliosis Orthopaedic and Rehabilitation Treatment (SOSORT)
- **Sashin Ahuja**, MD MSc (Spine registries)
Orthopaedic spinal surgeon, University Hospital of Wales, Cardiff, UK
Representative of the International Spine Registries working group
Committee member of the British Spine Registry (BSR)

Who can I contact in case of questions?

Contact the Spine Atlas Initiative (SAI) team at spineatlas@eurospine.org

Benefits for participants

Overarching benefits

- Reliable, real-life, and cross-border data to continuously monitor and improve the quality of their services and patient safety for all key stakeholders
- Providing a baseline for planning and developing health structures, education, research, and quality assurance
- Unique source of comparable diagnosis and treatment data for researchers worldwide
- Understanding the evolving magnitude and patterns of spine pathologies and treatments in different regions and countries.
- Evidence for the origins of variability across regions, which may it be due to environmental, behavioural, societal, medical school, guideline, or other reasons, and may show potential for improvement across multiple factors

What are benefits of the data submission for hospitals?

- Be a co-author in all key publications and/or participate in joint research projects,
- Understand distribution of spine pathologies and practice variation
- Join a large network of European hospitals, which may lead to various research projects and collaborations.
- Analyse and publish the data on their own (under certain terms and conditions approved by the Steering Committee).
- Receive a benchmarking report comparing their data with all other hospitals and countries.

What are benefits of the data submission for registries?

The international spine registries working group ISR, identified in the 2nd meeting of Spinal Registries in Frankfurt 2023 that a standardised core dataset should be collected in every spine registry. The Spine Atlas Initiative will test the availability and practicability of the use of the proposed core dataset in epidemiological studies.

The initiative supports and follows the further development in the harmonization of the data structures within registries.

Registries will also benefit from authorship in all key publications, the understanding of the distribution of spine pathologies and practice variation, and the approach to organise country-crossing collaborative epidemiological studies, combining data across multiple registries.

How can I participate?

Estimated efforts to share data:

- For a hospital: The effort to extract mandatory parameters from 20-40 average patients with lumbar degenerative spondylolisthesis per average unit over a 3-month period, as well as to complete the data quality survey, is expected to take approximately 2-3 hours in total.
- For a Spine Tango hospital: continued data collection, no data extraction effort, completion of data quality survey takes about 15 minutes.
- For an established registry: mapping parameters may be required, followed by data extraction of registry data and completion of data quality survey

How will data be submitted?

- For established spine registries: If requested data is routinely collected, the registry will be required to export the data and, if necessary, map it to the expected data structure, perform a plausibility and quality check, and share it with the SAI team over a secure connection.
- Hospitals using the Spine Tango platform: Complete and submit a brief survey. No additional efforts will be required, as the SAI team will extract the required data from the anonymised data pool based on the current Spine Tango Terms and Conditions and the consent of the respective participants. Hospital and individuals who are not part of an existing registry may either opt to use a trial version of the Spine Tango platform, see above, or may submit data using the Excel form provided after registration and submitted over a secure connection.

All data must be submitted via secure file sharing. The SAI team will provide you with the necessary details. All data will be stored in Access restricted, secure data storage and is only accessible to the SAI team.

When will I need to submit my data?

The data will be collected for patients treated from 1 February to 30 April 2025 and shall be submitted by 31 May 2025 to be analysed between June and August 2025.

When will the results be presented?

The results are expected to be presented starting August 2025

Data Analysis and publication

How will the data be combined and analysed?

All data will be combined by the SAI team with the support of NEC Software Solutions as EUROSPINEs IT and statistical service provider. Any non-anonymous data will be rejected and immediately deleted.

Each data submission will go through a basic validity check. The SAI team will confer with the submitter if problems arise. Summary statistics for each submission are produced and sent to the respective study participant.

For the rare occurrence of double submissions, i.e. simultaneous users of a national register and Spine Tango with different levels of detail, we will create comparison statistics, and the steering committee will decide how to incorporate the data.

How is the representativeness of the data submitted handled?

The data will be reported by country if deemed representative of the related country. The SAI steering committee will decide for each country if the coverage and representativeness of the data are sufficient to produce comparable single-country statistics for them. The steering committee will use the metadata survey answers from each participant to aid that decision. For details see section 11.5 in protocol

When and where will the data be published?

The results are expected to be published between August and December 2025. So far, two publications are planned, one to describe the infrastructure and collected data, and one with the results including the visualisation of pathology distribution and practice variation in the treatment of lumbar degenerative spondylolisthesis by country, “the maps”.

What will be the authorship?

In principle, two authors per data contributor will be permitted.

In detail, the following authorship positions are planned and will be reserved:

- First author: PI
- Contributing authors:
 - Study participants who significantly contributed to the manuscript
 - One statistician
- Senior author: author who has provided the most substantial intellectual contribution, which will be assessed by the first author and agreed upon all authors

All other persons including all data contributors and steering committee members, as not included above, will be listed as the Spine Atlas Working Group (SAWG). Max. 2 persons per data contributor/institution will be named, while all other persons assisting in data contributions will be listed in the acknowledgments. For registries more than 2 persons may be permitted on a case-by-case basis.

GDPR compliance and Data protection

How is compliance with the General Data Protection Regulation (GDPR) and other rules warranted?

The Spine Atlas Initiative SAI strictly follows all applicable data protection regulations.

On the side of the SAI team, only anonymous data will be accepted, non-anonymous data will be immediately deleted. Data is kept separate from normal operation and access is restricted to the SAI team only.

The participant, individual or organisation in the Spine Atlas data collection (the Participant) must ensure that they follow the requirements stated in the protocol and in [Appendix 1 “Terms and Conditions applicable to the collection and submission of data under the Spine Atlas Initiative”](#) and certify this on the participant survey accompanying the data submission. Participants need to ensure to collect informed patient consent from all patients that data is submitted for –unless not required by local law or regulations. Participants may use their own pre-existing consent forms if they are sufficient for that purpose or may opt to use the consent form template provided by the SAI team. Participants need to ensure that all necessary agreements are obtained from their institution in respect to any local laws, guidelines, ‘best practice’, ethical requirements, etc.

Preexisting users of the Spine Tango platform are additionally bound to the Spine Tangos Terms and Conditions, and trial users of the Spine Tango platform must accept the [Trial Terms and Conditions](#).

Do participants need to apply to their local ethics committee?

Participants must ensure that they follow any local laws, guidelines, ‘best practice’, ethical requirements, etc. Usually, the collection of fully anonymised data and usage for grouped summary statistics with prior patient consent is permitted. But as local rules and regulations may differ widely, the SAI team relies on the participant’s statement of compliance.

It is recommended to consult with other hospitals, institutions, and/or registries in your country to understand local requirements.

To support participants in case they need to seek formal ethical approval, the SAI team seeks additional index ethical approval from the local ethics committee of Eastern Switzerland for the collection and submission of SAI data. This will be made available on the website. Please contact the SAI team for more details about security if needed.

Should patients be informed and does the participating individual or institution need to obtain and document patient’s consent?

All SAI participants are required to ensure that patients for whom data is contributed were informed and have consented to their data being collected and used in anonymised form for summary statistics except for participants for whom local laws and regulations allow otherwise. The SAI team will not be able to control the participants’ compliance, and therefore the participation in the study will be subject to a statement of compliance.

Participants who have no own patient consent forms may use the templates provided by Spine Tango.

For existing Spine Tango participants, the use of data and all data and privacy protection issues are already outlined and governed by the Terms and Conditions for using the Spine Tango platform.

Will the participating individual or institution have to confirm that informed patient consent has been obtained?

The SAI participants are asked to confirm by ticking the respective box in the accompanying survey and Terms and Conditions, that permission is granted to use the data submitted for the purposes of the Spine Atlas Initiative and that patient consent was retrieved -unless not required by local law, i.e. for anonymised data from national registries.

Will patient-identifiable data be allowed, processed, or used in the Spine Atlas Initiative?

No patient-identifiable data will be allowed, processed, or used in the study, except optional numerical patient IDs. Other patient-identifiable data are not part of the requested data parameters to submit. If submitted, they will be rejected and deleted immediately.

Will hospital-level data be disclosed in the study?

Hospital-level data will not be disclosed in the study except for confidential hospital reports, which will only be shared with the involved hospital.

Will the collected and pooled data be used for another purpose than the Spine Atlas Initiative?

No. The anonymized collected and pooled data will be used solely for purposes of the SAI. Within the SAI, any participant is invited to propose further research questions to be answered with the help of the collected and pooled data. The steering committee will decide on the request, the SAI team will perform the analyses, the proposing participant is invited to be a lead author on the resulting manuscript, all data contributors are to be included in the group authorship according to rules set in the SAI protocol.

Will patient-identifiable personal data be collected or released?

No patient-identifiable personal data may be collected or released.

Can hospital-identifiable data be released?

Hospital-identifiable data may only be released upon prior consent of the releasing hospital.

Can patient-level data without patient-identifiable personal data be used?

No patient identifiable data is permitted to be made available in the SAI. Patient level data will be grouped for all analyses.

In general, patient-level data without patient-identifiable personal data may only be collected if a data use agreement is in place. Spine Tango and trial Spine Tango users have such agreements in place. However, this data is not available to the SAI. For all other participants, the SAI-agreement states that no patient-identifiable personal data may be collected or released in the Spine Atlas Initiative.

What data will be collected in the Spine Atlas data set?

The Spine Atlas data is comprised out two data sets, one mandatory, the second optional:

In short, the mandatory parameters are:

1. Patient age at surgery date (in whole years)*
2. Patient gender
3. Surgery date
4. Primary spine surgery at the same or adjacent level
5. Type of spinal stenosis (central or lateral, foraminal)

6. Grade of LDS (a) by Meyerding (b) OR in mm
7. Surgical measures
 - o (if any) (a1) Decompression type and (a2) level
 - o (if any) (b1) Fusion type and (b2) level
 - o (if any) (c1) Stabilisation rigid type and (c2) level
 - o (if any) (d1) Dynamic stabilisation and (d2) level
 - o (if any) (e1) Other surgical treatment (e2) level

The optional parameters are:

8. Additional spinal pathology
9. ASA status
10. Number of previous spine surgeries at the same or adjacent level
11. Duration of symptoms
12. (a) Height and (b) weight (c) OR alternatively BMI
13. Current smoker status
14. (if any) (a) Data on the implant manufacturer and (b) article number

*age may be permitted to be sent in age groups if required by local data protection law. Please contact the SAI team (spineatlas@eurospine.org).

How will the Spine Atlas Data retention and data security be ensured?

The received and processed data will be kept separate from normal operations in the SAI project team.

It will be stored without personal data -that was removed at data collection- on a Swiss based secure cloud with access control. Access will be only granted to the SAI project personnel.

How long will the Spine Atlas Data be retained?

Data will be kept for a period of 15 years after completion of the study.

[Additional FAQ for Spine Atlas participants collecting data using Spine Tango](#)

Are there additional General Terms & Conditions for using Spine Tango?

Yes, SAI participants who wish to use Spine Tango for collecting data must apply for the use of Spine Tango and sign and comply with the Spine Tango General Terms & Conditions, including the one for collecting informed patient consent. SAI participants are all entitled to obtain full access subscription to the Spine Tango registry for a limited trial access by clicking and accepting the Spine Tango registry Terms and Conditions [here](#).

Is there a template Spine Tango Patient Informed Consent document available?

Yes, this can be downloaded in several languages from EUROSPINE website [here](#).

Where can I find the Spine Tango FAQ on data protection and information security?

Please refer to Annex one of the Spine [Tango General Terms & Conditions](#).