schweizerisches implantat-register
registre suisse des implants

SIRIS

SIRIS Spine – Swiss spinal implant registry
Concept (version dated 5/ 26/ 2020, v. 1.0)

Development in cooperation between:
Swiss Orthopaedics (SO)
Swiss Society of Neurosurgery (SSNS)
Swiss Society of Spinal Surgery (SSSS)
as well as
SIRIS Spine Steering Group
SIRIS Spine Scientific Advisory Board
ANQ – Swiss National Association for Quality Development in Hospitals and Clinics

Contents

May 26, 2020

anq EUROSPINE swiss orthopaedics SCHWEIZERISCHE GESELLSCHAFT FÜR NEUROCHIRURGIE SOCIETE SUISSE DE NEUROCHIRURGIE SOCIETA SVIZZERA DI NEUROCHIRURGIA SWISS SOCIETY OF NEUROSURGERY www.swissneurosurgery.ch SGS Schweizerische Gesellschaft für Spinale Chirurgie Société Suisse de Chirurgie Du Rachis Società Svizzera di Chirurgia Spinale Swiss Society of Spinal Surgery

1. Starting situation

In 2015, the partners of the National Quality Agreement (H+, santésuisse, the Medical Tariff Commission UVG and the Conference of Health Directors) approved the proposals put forward by the ANQ regarding the incorporation of the spinal implant registry SIRIS Spine into the ANQ review plan. The professional organizations Swiss Orthopaedics (SO), the Swiss Society of Spinal Surgery (SSSS) and the Swiss Society of Neurosurgery (SSNS) are fully committed to measures that improve quality in the field of spinal surgery and decided to hand over the administration, contracts, organization, financing and adoption of the legal structure to the SIRIS foundation. This means that SIRIS Spine is administered under the same legal and organizational provisions as the SIRIS Hip & Knee implant registry, which has been mandatory for eight years. In 2019, under the leadership of the SIRIS foundation together with the three professional associations, two relevant registry operators were evaluated in terms of their range of services, potential and costs. The decision was made in favor of EUROSPINE and Northgate.

The concept presented here describes the main features of SIRIS Spine with regard to the legal framework, data protection and security, interfaces with Spine Tango, data structure and quality, registering primary surgery and tracking revisions and reoperations, evaluation methods and data reporting, as well as hosting, the registry platform, the team and technical service model, implementation planning and financing.
The development of SIRIS Spine follows the recommendations for the development and operation of health-related registries.

The aim of SIRIS Spine is to develop a solid national database for quality assurance and to collect data that is compatible with Spine Tango data in order to enable international comparisons in spinal surgery and to prevent duplicated entries from clinics.

2. Contract and project partners of the SIRIS foundation

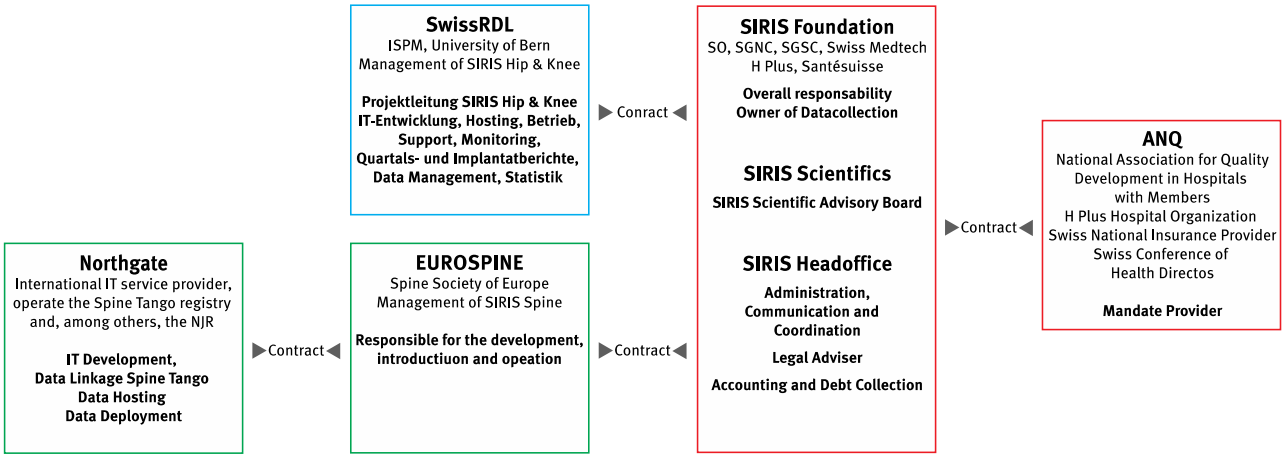
SIRIS The Foundation for Quality Assurance in Implant Surgery SIRIS is an independent, non-profit organization. The Foundation Board is made up of equal numbers of delegates from the organizations Swiss Orthopaedics, Swiss Medtech, the hospital organization H+ and santésuisse. SIRIS was founded in August 2007 and subsequently established the Swiss implant registry SIRIS Hip & Knee. Since 2012, SIRIS Hip & Knee has formed part of the ANQ review plan and has been compulsory for hospitals that have signed the National Quality Agreement and that list these two procedures in the catalog of services they offer. The same will apply for SIRIS Spine from 2021.

ANQ is a national association for quality development in hospitals and clinics. Its members are the hospital organization H+, santésuisse, curafutura, the Swiss social insurance providers, the cantons and the Swiss Conference of Health Directors. Under the ANQ's National Quality Agreement, clinics are required to implement and finance the defined quality measures. The ANQ has concluded a service agreement with SIRIS.

SwissRDL, part of the ISPM at the University of Bern, specializes in medical registries and data linkage. SwissRDL manages the technical implementation, support for hospitals, data management and statistical evaluation of SIRIS Hip & Knee on behalf of the SIRIS foundation.

EUROSPINE, the Spine Society of Europe based in Switzerland, has 1,500 active members and over 7,000 associate members. It owns and manages the Spine Tango registry and is responsible for the development, introduction and operation of SIRIS Spine within a contractually defined scope.

Northgate is an international IT service provider with headquarters in the UK and operates the Spine Tango registry on behalf of EUROSPINE. It also manages the British National Joint Registry (NJR), among others. Northgate is developing a customized IT solution for SIRIS Spine on the basis of Spine Tango. The cooperation with EUROSPINE and Northgate guarantees the use of a standardized implant library and simplified access to a European data pool.



3. Key elements of SIRIS Spine data collection

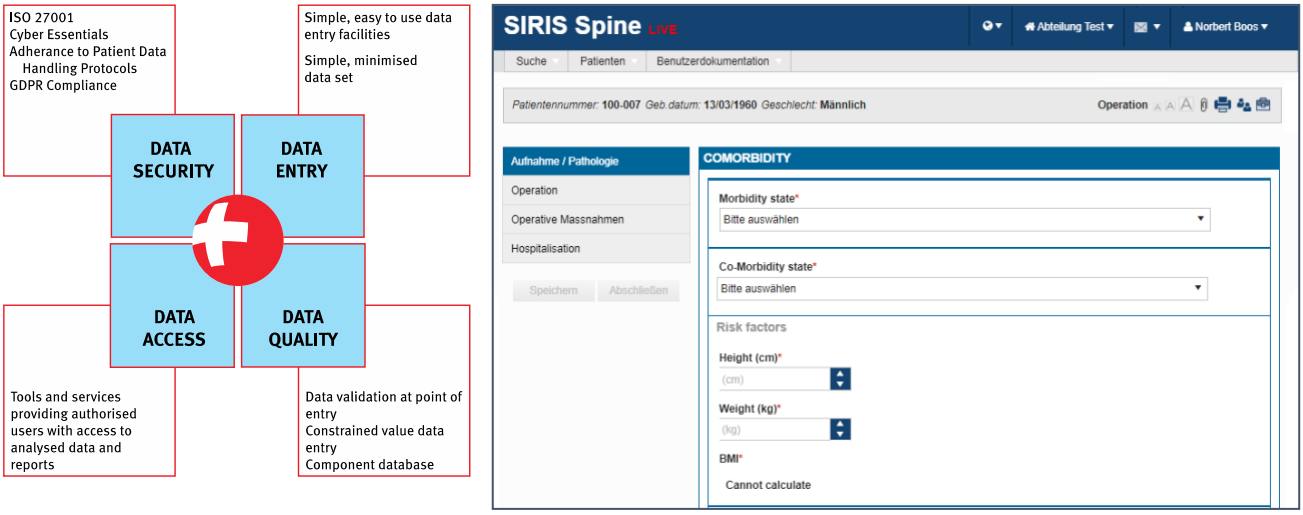
Simple data input Collection of an agreed data set by means of a simple, flexible and easy-to-use online platform. The documentation system only allows the user to input data using restricted lists of valid values. No paper forms are used.

High data quality At the point of being input, the data is checked for plausibility in order to ensure "valid values" for the data set. Non-applicable question and answer elements are hidden, i.e. they are excluded from the process of data documentation, which keeps the documentation process lean. The implant data are registered directly from the catalog with the specifications used by the industry to guarantee unambiguous identification and classification of the implants.

Data access and reporting Optimized instruments and tools are made available to enable authorized users to access data and reports easily. In addition to an annual, publicly available SIRIS Spine Report, quarterly reports for clinics form part of the reporting process. Clinics have the option to download their own data elements at any time.

Data security The security of the registered data is of fundamental importance, as is the registry's compliance with the Swiss Federal Act on Data Protection (FADP) and the General Data Protection Regulation (GDPR) of the European Union that protects the rights of European citizens. SIRIS Spine follows the same security standards as the existing SIRIS Hip & Knee register.

Fundamental key elements and input screen (draft) of SIRIS Spine



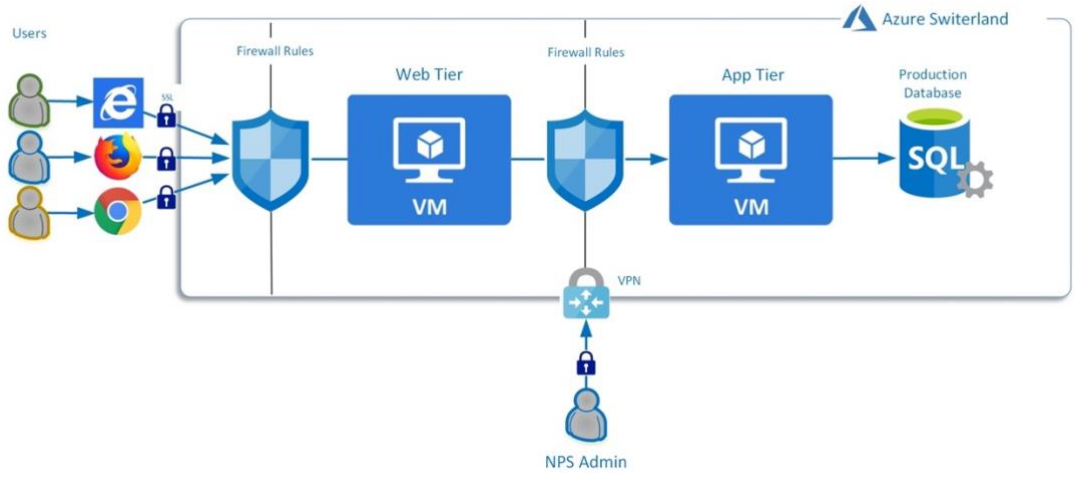
4. Data protection and security

Principles of data access The registry stores all data centrally; however, the medical data components are separated from the data components that allow patient identification. The only people who have access to data identifying patients are the attending physician and the certified Northgate employees with the appropriate security clearance who are responsible for carrying out necessary activities. The employees of individual clinics with access rights are only able to access the data of their own clinic and patients. An admin function enables access to the aggregate data of a clinic. With regard to data protection and patient consent, SIRIS Spine follows the concept currently being introduced by SIRIS Hip & Knee (written consent is obtained from the patient before the procedure). Issues of data protection, data sovereignty, inspection rights, further use of the data by third parties, etc., are defined in detail in a separate document setting out regulations for use.

Accreditation Northgate is certified in accordance with ISO/IEC 27001:13, ISO/ISEC 9001 and the British government's Cyber Essentials scheme. Northgate also complies with the Information Technology Infrastructure Library (ITIL) and the NHS Information Governance Toolkit (required for processing NHS data).

Information governance The owner of the data collection (the SIRIS foundation) and the registry administrator (Northgate on behalf of EUROSPINE) have contractually defined governance processes for the processing of data. The registry administrator will operate at all times on express instructions from the SIRIS foundation. All requests for Swiss spine data are forwarded to the SIRIS foundation for review and approval. Northgate/EUROSPINE will only pass on data to third parties if this has been approved by the SIRIS foundation. The data is hosted on a server in Switzerland (Microsoft Azure).

Physical IT infrastructure



5. Northgate registries platform and service delivery

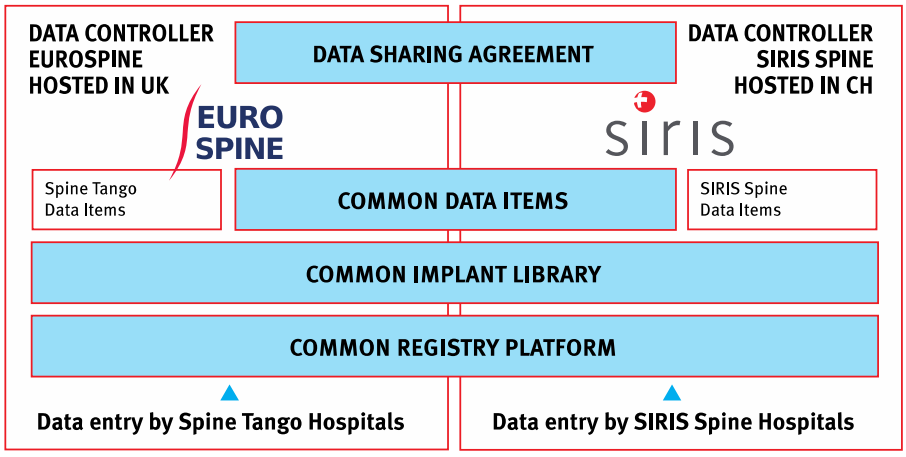
The registries platform provided by Northgate has been specially developed for the collection and analysis of data related to treatments involving medical products, such as hip, knee and spinal implants. The platform is configured to correspond with the specific requirements of SIRIS Spine and will use the same implant database as Spine Tango. The Northgate registries platform is a web application; all the end user needs is access to the internet and a compatible browser (Chrome or Firefox). The Northgate registries platform will use the GS1 barcode standard for the scanning of implants with barcodes. The platform adopts a modular approach with support for future development such as PROMs, specific analyses and new features and fields.

6. SIRIS Spine and Spine Tango

SIRIS Spine and Spine Tango will use the same basic data set. While the two registries are operated independently of each other, there are substantial benefits to close cooperation between them:

- A shared, reliable registries platform and database for implants (implant library)
- Further development of features for both registries available simultaneously
- Rapid attainment of statistically robust statements as a result of data pooling
- Existing document templates (study protocol template, user documentation, etc.)
- No duplicated data entry for Swiss Spine Tango clinics

Separation between Spine Tango and SIRIS Spine



7. Patient group and data structure

In the first stage from 2021, the plan is to record the most common lumbar spine procedure (ca. 4,500 cases per year in Switzerland) – dorsal lumbar spinal fusions with pedicle instrumentation (one to two segments):

- Lumbar or lumbosacral arthrodesis with dorsal access (intervertebral or dorsolateral access)
- PLIF (posterior lumbar interbody fusion)
- TLIF (transforaminal lumbar interbody fusion)

SIRIS Spine variables and data structure

yellow	patient data
green	Additional diagnostic group
white	clinical data single choice question
blue	clinical data multiple choice question
read	Only if repeat surgery

Question text	Answer text
Social Security Number (optional)	Number
Patient first name	Patient first name
Patient last name	Patient surname
Patient last name at birth if different	Patient last name at birth if different
Gender	male
	female
	other
	not specified
Patient birthdate	Patient birthdate
Patient email address	Email address
Patient phone number	Phone number
Patient home address	Address
Place of birth	Place of birth
Country of birth	Country
Medical Record Number (MRN; hospital internal)	Number
MAIN PATHOLOGY	3 Options 1- deg. disease, 2- spondylolisthesis (non-degenerative), 3- repeat surgery
DEGENERATIVE DISEASE: primary type	single choice
DEGENERATIVE DISEASE: secondary type	multiple choices
Additional window if main pathology: **SPONDYLOLISTHESIS: TYPE**	single choice
Additional window if main pathology: **SPONDYLOLISTHESIS: grade**	single choice
If main pathology = repeat surgery **REPEAT SURGERY: reason**	multiple choices
No. of previous spine surgeries at the same level(s)	single choice

Question text	Answer text
Height	(cm)
Weight	(kg)
Current smoker	single choice
Co-morbidity state	single choice
Surgery date	surgery date
Surgeon name	surgeon name
Instructed surgery	single choice
Posterior access	single choice
If main pathology = repeat surgery **Anterior access**	single choice
Decompression	multiple choice
Extent of surgery of decompression	multiple choice
Fusion type	multiple choice
Fusion material	multiple choice
Extent of surgery of fusion	multiple choice
Stabilization rigid	multiple choice
Extent of surgery of rigid stabilization rigid	multiple choice
If main pathology = repeat surgery **Deformity correction**	single choice
If main pathology = repeat surgery **Extent of of deformity correction**	multiple choice
Other surgical measures	multiple choice
Intraoperative adverse event	multiple choice
If intraoperative adverse event, then **Measures during surgery**	multiple choice
Intraoperative general complications	multiple choice
Components	BAR Code scanning: name and article number out of catalogue (for every implant)

8. Data quality and data validation

Training The use of the data input system of SIRIS Spine will be explained by means of training materials and video tutorials. Support for questions is also available (within office hours on three days a week, in German and French).

Data validation The system checks the validity of answers (and answer combinations) and only allows plausible entries; it issues a warning when the data entered could be implausible. EUROSPINE is working together with the SIRIS Spine Scientific Advisory Board to determine and configure the necessary validation rules for the SIRIS Spine data input. Each implant that is linked with an entry in the registry also has a link to the implant database, which ensures that every implant is referenced using the unique reference number allocated by the manufacturer.

Monitoring data quality Northgate continuously monitors the quality of the data that is entered in the registry. Any problems identified are returned to the relevant clinics by EUROSPINE for subsequent processing via a report on data quality, and any common themes identified are used to develop new validation rules. In addition, regular audits are carried out on site to evaluate and monitor the clinics' documentation quality. The validation concept, which is still to be developed, will explain the details of these quality measures.

Reporting on data quality SIRIS Spine issues a personalized data quality report to each participating clinic on a yearly basis. The aim of the data quality report is to give each organization an assessment of the completeness and quality of the data they have submitted, identify common problems or patterns in local data transmission and offer support for solving these problems. The data quality report will contain the following:

- Number and completeness of registered cases that are still open
- Notes on the missing data
- Information on the data quality of registered data, e.g. an analysis of implausible data that was accepted by overriding the data entry system

9. Tracking revisions and reoperations

Reoperations and revisions can be linked to primary operations in different institutions as the clinic and/or surgeon may change between operations. Like SIRIS Hip & Knee, SIRIS Spine uses an identifier not bound to a single clinic (based on the patient's name, date of birth, sex and place of birth), which means that the accuracy of revision rates can be calculated reliably. Data from the FSO register of deaths is also used to clean up the revision rates in the registry.
The correct identification of a revision or reoperation primarily depends on it being correctly recorded by the surgeon. To check the data for plausibility, SIRIS Spine demands the CHOP codes of the clinics involved. By comparing this with the registrations received, the registration rate can be calculated. The clinics are informed of their results quarterly.

10. Reporting

Quarterly report The quarterly reports are made available to the clinics in a standardized form (incl. benchmarking). The content of this report is continually adapted to the requirements of the clinics. The report content is developed by the SIRIS Spine Scientific Advisory Board and subsequently subject to consultation and final approval from the ANQ and the SIRIS foundation. The content of the report includes:

- Revision rates by clinic and implant, including indications for revision
- Risk factors for revision operations
- Rate of epifusional and subfusional reoperations
- Implant-related complications and implant failure rates

SIRIS Spine Report As soon as the data situation allows, a comprehensive SIRIS Spine Report will be produced and published annually. This provides the basis for the ANQ to generate the contents of a short report, for which the ANQ holds the primary publication rights. The aim of the reporting process is transparent publication at the level of clinics. To this end, the SIRIS Spine Scientific Advisory Board will develop a publication concept in close cooperation with the SIRIS foundation and the ANQ.

11. Project organization and communication channels

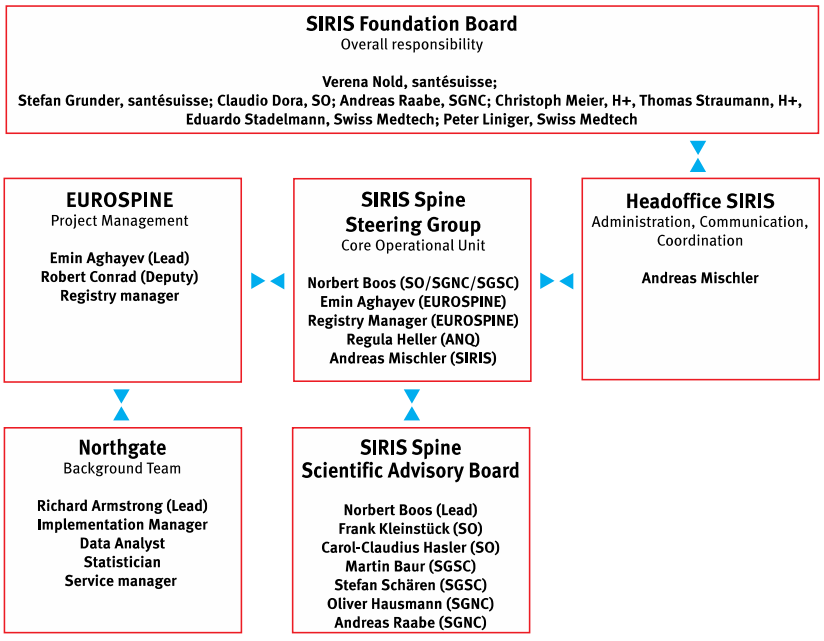
The **SIRIS Spine Steering Group** is the core operational unit during the development phase and reports to the SIRIS Foundation Board as well as the ANQ. It is made up of the following people:
Prof. Norbert Boos (SO/SSSS/SSNS), Dr. Emin Aghayev (EUROSPINE), Regula Heller (ANQ), Andreas Mischler (SIRIS foundation).

The **SIRIS Spine Scientific Advisory Board** is consulted by the Steering Group on issues of content and is responsible for the definition of the variables to be recorded as well as the definition of focus areas in the evaluation, incl. the evaluation concept and the report contents. The Board will also guide the stages of expansion from 2022 to 2024. It is currently made up of the following people:
Prof. Norbert Boos (SO), Chair
Dr. Frank Kleinstück (SO), Prof. Carol-Claudius Hasler (SO), Dr. Martin Baur (SSSS)
Prof. Stefan Schären (SSSS), Dr. Oliver Hausmann (SSNS), Prof. Andreas Raabe (SSNS)

EUROSPINE is responsible for the project management, planning, system configuration and implementation consulting, as well as the quality assurance, support, maintenance, user support and operation of SIRIS Spine. Dr. Emin Aghayev takes on the **project management** on behalf of EUROSPINE; he is responsible for ensuring that deadlines are met and that SIRIS Spine achieves its aims. A deputy is assigned to the project manager.

The user support for SIRIS Spine is the responsibility of the **registry manager**. This post will be filled by January 2021 at the latest. The registry manager performs regular on-site audits of the clinics in accordance with the validation concept and is a member of the SIRIS Spine Steering Group.

The **background team** is put in place by Northgate and is responsible for ensuring that the registry is fully functional. The clinics do not communicate directly with the background team; they do this via the registry manager.



12. Implementation and schedule

Project phases in 2020

- Implementation June/July/August
- Testing August
- Pilot expected September – November 2020 in selected clinics
- Finalization during and on completion of the pilot phase
- Realization January 2021

Implementation In this phase, the development and test environments are set up and configured for the IT environment in Switzerland.

The reusable components of Spine Tango

- User administration, user authentication, authorization
- Control mechanisms, search, exports, multiple languages of the registry platform, image upload, etc.
- GS1 barcode standard
- User area for reports
- Implant catalog with queries to the implant companies in the case of missing implant specifications

The new technical developments and configurations

- Access website with SIRIS Spine brand
- User interface (GUI)
- QR code generator
- Identifier not bound to clinic (based on details identifying patients)
- SIRIS Spine data structure
- Data recording screen in combination with the Spine Tango data structure as well as physical separation between SIRIS Spine and Spine Tango data
- Checking for completeness and possible completion of the implant database with data from implants on the Swiss market
- Patient consent in the four national languages and English
- User documentation and dictionary of terms
- Setting up user accounts of the pilot clinics
- Training for pilot clinics

Testing The tests carried out by Northgate include a complete set of system, performance and integration tests for the application, with simulated user loads to ensure that the solution will function

as expected when used in a live environment. In addition, user acceptance testing (UAT) will provide prompt feedback. EUROSPINE will deliver training on how to use the application to a core team from the SIRIS Spine Scientific Advisory Board.

Pilot The aims of the pilot phase are set out in the following table.

No.	Pilot aims	1. month	2nd month	3. month
1	The complete and comprehensible training content is communicated. The defined introduction process takes all key aspects necessary for registering data into account.	x	-	-
2	The feasibility of comprehensive recording is checked; possible stumbling blocks and risks are identified.	-	x	x
3	The user friendliness of the input screens and the user guidance in the documentation process are checked.	x	x	x
4	The documentation (DE and FR) are checked for completeness and comprehensibility.	x	x	x
5	All other relevant requirements for introduction at the national level are checked. Before introduction at the national level, any problems and challenges are identified and countermeasures are determined and implemented.			x

In this phase, the following products and services are finalized and piloted and/or tested:

- User documentation
- Setting up user accounts, training and support for the pilot clinics
- QR code generator
- Admin function monitoring of the clinic or hospital's registration activities

At the start of the pilot phase, the pilot clinics will have the opportunity to record some initial cases in a training environment and subsequently register the clinical data from everyday practice in a live environment. The aims listed are regularly analyzed. In this phase, the validation concept and the first draft of the quarterly report are also developed in cooperation with the SIRIS Spine Scientific Advisory Board.

Finalization In this phase, the findings from the pilot phase are implemented, the user documentation is finalized in the three official languages and English, the first version of the evaluation concept is developed and the necessary further development of the registration platform is undertaken.

Realization The clinics are informed of the compulsory quality measurement multiple times beforehand. They are assigned clinic registration details with information concerning the number of cases expected and the implants used. A series of training sessions using a video conference format are offered in advance. The registry manager takes over from the project manager and assumes responsibility for service delivery. They are available to answer users' questions. User support is offered in German, French and English. In this phase, initial monitoring of the clinics and hospitals is carried out. Data quality reports and the quarterly reports can be issued starting from the first year.

13. SIRIS Spine data sets from the user's perspective

The users of SIRIS Spine can be divided into two groups:
Group A: those who will only document the compulsory content of SIRIS Spine
Group B: those who will additionally document the remaining questions of Spine Tango as well as potentially other forms (such as COMI, Oswestry, NDI, medical follow-up examination, conservative treatment, etc.). Both user groups will have just one data input point: the SIRIS Spine website.
SIRIS Spine is designed so that Group B do not have to enter any data twice – they can enter the content of SIRIS Spine and additional Spine Tango questions and/or other forms.
The historical data from Swiss clinics will be migrated from the Spine Tango registry onto the Swiss infrastructure, meaning it can be retrieved using the same data input point as SIRIS Spine. The data migration is expected to be performed toward the end of 2020, shortly before the introduction at national level.

14. Ownership of the data collections

The SIRIS Spine data collection is owned by the SIRIS foundation. This data collection is hosted in Switzerland and contains patient data (orange), medical data that is technically or semantically compatible between SIRIS Spine and Spine Tango (green) and data that is specific to SIRIS Spine (in blue), as shown in the following simplified depiction.
The Spine Tango data collection is owned by EUROSPINE. The data collection is hosted in the UK. Spine Tango regularly receives a physical copy of medical and selected patient data (year of birth and gender) that is technically or semantically compatible between SIRIS Spine and Spine Tango (in green) as well as the other non-compatible data that is specific to Spine Tango (in gray).
No patient data leaves Switzerland apart from the year of birth and gender. The compatible data (in green) is used for reporting in Spine Tango and in SIRIS Spine on the basis of merged data sets.

SIRIS Spine	Spine Tango
Patient details (first name, last name, date of birth, internal hospital identification number, etc.)	Anonymous, system-generated patient ID
Gender Year of birth Main pathology - Degenerative disease - Reoperation Risk factors (ASA, smoker status, BMI) Treatment types Implant data Complications Other compatible data	Gender Year of birth Main pathology - Degenerative disease - Reoperation Risk factors (ASA, smoker status, BMI) Treatment types Implant data Complications Other compatible data
Specific individual expressions in: Diagnosis Comorbidities Revision techniques	Other main pathologies - Trauma, infection, deformity, etc. Technology Qualification of the surgeon Operation time Blood loss Other non-compatible data

15. Financing

The SIRIS foundation is responsible for financing the development of the registry. The costs of operating the registry are covered through the clinics by means of registration contributions. As the area applicable to SIRIS Spine involves small numbers and a complicated structure, a maximum cost of CHF 50 per registration is expected.
Based on a self-assessment (expected number of cases), the clinics are issued with an invoice for the operations in the defined field of the quality measure twice a year (2021: CHOP codes 7A.71.11, 7A.71.12, lumbar spine procedures with dorsal pedicle instrumentation for one to two segments for degenerative disorders of the spine). The invoice amount is checked the following year using FSO numbers and registrations. This then results in a retrospective invoice or a credit.

16. Stages of expansion of SIRIS Spine

The following stages of expansion are envisaged for the coming years:

- Percutaneous vertebroplasty (PVP) and kyphoplasty (PKP) (ca. 5,000 cases/year from 01/01/2022)
- PROMs (COMI and EQ-5D) (from 01/01/2023, test phase 2022)
- Cervical and ventral spinal fusion (ca. 1,500 cases/year) (from 01/01/2023)
- Newly introduced spinal implants (from 2024/5)

In a one-year test phase from 2021, the COMI score used in Spine Tango, in combination with EQ-5D where applicable, will be collected as a PROM in about five clinics. When recording this patient-based output data, findings relating to the time required and the associated costs and infrastructure should be collected.

The stages of expansion are an essential component for the financing of the SIRIS Spine implant registry. This is the only way that the critical threshold of registration numbers will be reached so that the operation of the registry can become self-financing. The SIRIS foundation is taking on the deficits that are to be expected during the initial years of development, but these must be refinanced again in the long term.

June 29, 2020, SIRIS Spine Steering Group