SOCAS
Swiss OutCome After Anaesthesia and Surgery

A National Quality Project to Improve Perioperative Safety and Outcomes in Switzerland

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Project Summary

Introduction

SOCAS is a national, prospective, observational quality project that aims to evaluate perioperative morbidity and mortality in Switzerland. Despite considerable progress in anesthetic and surgical practices, reliable and comprehensive national-level data on perioperative outcomes are lacking. The SOCAS project addresses this limitation by combining clinical outcome data from the A-QUA (Anaesthesia QUAlity) program with institutional quality assessments from the A-CERT (Anaesthesia CERTification) framework. This dual-source model enables efficient, standardized data acquisition within routine clinical processes while leveraging existing quality infrastructure to support benchmarking and targeted improvement initiatives.

Background

Perioperative morbidity and mortality are recognized as indicators of the quality and safety of healthcare. In Switzerland, however, outcome data remains incomplete and fragmented. Although the Federal Office of Public Health (BAG) reports in-hospital mortality rates for certain procedures, there is a lack of national-level data on postoperative complications and anesthesia-related adverse events. Estimates based on closed-claim analyses substantially underrepresent the true burden of complications and provide little basis for quality improvement.

To address this issue, the Swiss Society for Anesthesiology and Perioperative Medicine (SSAPM) has established two national quality initiatives.

- A-QUA: A structured digital platform that captures routine perioperative clinical data at the institutional level.
- A-CERT: A national certification and audit program that assesses the structural and procedural quality of anesthesia departments.

SOCAS combines these two components to produce reliable, real-world data on perioperative outcomes and institutional quality across a sample of hospitals that is representative of Switzerland.

Aim

The primary aim of SOCAS is to evaluate the morbidity and mortality of Swiss patients undergoing anesthesia, whether or not they undergo surgery. The study also aims to facilitate benchmarking across institutions and contribute to national initiatives aimed at improving the quality and safety of perioperative care.

Primary Objectives

- To quantify in-hospital and 180-day all-cause mortality in the perioperative population.
- To assess intraoperative and postoperative complications using standardized classification tools (e.g., ClassIntra, Clavien-Dindo).
- To describe the incidence of specific adverse events, such as postoperative delirium and prolonged length of stay.

- To explore the associations between perioperative outcomes and risk factors related to patients, surgery, and anesthesia.
- To compare outcome variation across participating institutions, including A-CERT-certified centers.
- To provide data-driven feedback for institutional and national quality improvement efforts.

Study Design

- **Type**: Prospective, multicenter observational cohort study
- **Setting**: Minimum 10 Swiss hospitals participating in the A-QUA program, including multiple A-CERT-certified centers
- **Population**: All patients receiving anaesthesia, with or without surgery
- **Sample size**: Approximately 40,000 patients
- **Duration**: 3–6 months of data collection; 180-day follow-up

Data Collection and Management

Data will be collected through the A-QUA platform and supplemented with project-specific variables:

- Patient demographics and risk profile
- Anaesthesia and surgical characteristics
- Intraoperative events (ClassIntra)
- Postoperative complications (A-QUA 24h, Clavien-Dindo)
- Postoperative delirium
- Length of stay (ICU, hospital)
- Mortality at discharge and at 180 days

Data are pseudonymized upon entry and managed centrally in accordance with national data protection requirements. Site-level coordination is facilitated by designated quality officers or study nurses.

Feasibility

SOCAS is embedded within the existing national quality infrastructure, ensuring high feasibility:

- Participating centers already collect routine data through A-QUA.
- Many institutions are A-CERT certified, demonstrating quality system readiness.
- Data collection aligns with clinical workflows and requires no intervention.
- Prior experience of the study leadership in large-scale outcome studies supports operational reliability.

The estimated sample size can be achieved within the planned data collection period with minimal additional resources.

Ethical Considerations

SOCAS is a non-interventional quality initiative using pseudonymized data from routine care. Under Swiss legislation (HFG Art. 34 / HFV), individual patient consent may not be required. Nonetheless, the study will be submitted to the Ethics Committee of the Canton of Zurich (KEK

Zurich) as the lead ethics authority. Data handling will fully comply with applicable privacy and data protection regulations.

Relevance

SOCAS represents the first national initiative in Switzerland to combine real-time perioperative outcome data (A-QUA) with external quality certification (A-CERT). Its findings will:

- Enable outcome benchmarking across institutions
- Support targeted quality improvement
- Validate certified centers as reference models
- Contribute to national standards and guidelines in perioperative medicine
- Establish a foundation for ongoing quality surveillance and research

Contact and Leadership

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The project is conducted by the SOCAS Study Group on behalf of the Stiftung für Patientensicherheit in der Anästhesie (SPSA), in collaboration with the Swiss Society for Anaesthesiology and Perioperative Medicine (SSAPM).

Advisory Board

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1. Background

Perioperative morbidity and mortality are still important indicators of the quality of healthcare and patient safety. Despite advances in anesthesia and surgical practices that have improved outcomes in recent decades, significant variability persists. International observational studies have revealed substantial variations in complication and mortality rates among institutions and countries, which are frequently attributed to differences in perioperative management systems, infrastructure, and adherence to evidence-based protocols.

The European Surgical Outcomes Study (EuSOS) revealed that, in 2012, 7-day postoperative mortality rates across Europe ranged from 1.2% to 21.5%, averaging 4% (Pearse et al., 2012). The 2016 International Surgical Outcomes Study (ISOS) found an overall morbidity rate of 16.8% and a postoperative mortality rate of 0.5% following elective surgery in 27 countries (ISOS Study Group, 2016). Notably, patients who developed postoperative complications had a significantly higher mortality risk, at 2.8%, highlighting the importance of preventing and detecting complications early.

In contrast, anesthesia-related mortality in high-income countries is significantly lower and has steadily decreased over time. Between 1990 and 2000, studies reported an anesthesia-related death rate of approximately 1 in 40,000 (Bainbridge et al., 2012). More recent data from France reported an overall mortality rate attributed to anesthesia of 1 in 145,000 (Lienhart et al., 2006), while a mortality rate partially attributed to anesthesia reached 1 in 21,000. Anesthesia-related severe complications occur in 0.01% to 0.03% of cases (Tiret et al., 1986; Kawashima et al., 2003), while minor complications affect 18% to 23% of patients (Bothner et al., 2000; Fasting & Gisvold, 2003).

However, national data on perioperative outcomes in Switzerland remain incomplete. The Federal Office of Public Health (BAG) provides limited mortality statistics for a few surgical procedures. Between 1998 and 2014, they reported postoperative mortality ranging from 0.1% for hysterectomy to 11.1% for lower limb amputation, with an overall average of 1.4% (Wacker & Zwahlen, 2019). In the Swiss subset of the EuSOS, the country-specific 7-day postoperative mortality rate was 2% (Pearse et al., 2012). Importantly, these reports do not include data on postoperative complications or anesthesia-specific events. The only available insights into anesthesia-related morbidity and mortality come from closed-claims analyses, which are limited in scope and likely underreport real-world events. For example, one analysis covering 1987–2008 recorded only eight claims per year, or one claim for every 122,000 anesthetic procedures (Staender et al., 2011).

Efforts to collect perioperative data in Switzerland began with the Anesthesia Databank Switzerland (ADS), which operated from 1996 to 2006. Although the ADS successfully collected up to 275,000 datasets annually from 41 institutions, the project encountered difficulties with data integrity, database adaptability, and incomplete follow-ups. These issues ultimately limited the ADS's ability to support outcome-based quality analysis (Pittet et al., 2013).

In response, the Swiss Society for Anesthesiology and Perioperative Medicine (SSAPM) created two significant national quality assurance tools.

- **A-QUA (Anaesthesia QUAlity):** a structured, modular digital database for capturing perioperative process and outcome data using a standardized variable catalogue (n ≈ 158).

- **A-CERT (Anaesthesia CERTification):** a national certification program for anaesthesia departments based on peer-reviewed audit criteria, covering infrastructure, governance, education, and adherence to safety protocols.

A growing number of institutions now use A-QUA, which provides real-time, pseudonymized perioperative data and - in the future - will provide data on intraoperative events (e.g., via the ClassIntra scale), and early postoperative outcomes (e.g., A-QUA 24h, Clavien-Dindo classification, delirium, and length of stay [LOS]). On the other hand, A-CERT functions as a process-based quality framework that validates institutional readiness and quality maturity.

These developments present a new opportunity to create a scientifically robust and clinically embedded national dataset. The SOCAS initiative leverages this dual infrastructure to create the first comprehensive dataset on perioperative outcomes as well as surgery and anesthesia safety in Switzerland.

2. Rationale

The primary rationale for SOCAS is to address the lack of standardized, risk-adjusted, nationally representative data on perioperative outcomes in Switzerland. Current national indicators are limited in scope, fail to include postoperative complications, and are not integrated with anesthesia-specific data sources. Without a coordinated national registry, benchmarking, risk modeling, and systematic quality improvement are difficult to achieve.

SOCAS is designed as a non-interventional, observational quality project. It integrates two established components:

- **A-QUA** provides high-volume, prospective clinical data from routine practice.
- **A-CERT** ensures structural quality and institutional audit-readiness among participating centers.

This dual framework allows for comprehensive analysis of perioperative risk, morbidity, and mortality. It also enables stratified comparisons across institutions and patient subgroups, using standardized tools such as the ClassIntra scale, Clavien-Dindo classification, and postoperative delirium indicators after their implementation.

Key advantages of SOCAS include:

- Use of pseudonymized data collected within existing clinical workflows.
- Feasibility and scalability based on A-QUA and A-CERT.
- Potential to inform benchmarking, certification, and targeted feedback for quality improvement.
- Contribution to a learning health system approach, linking data to practice.

Integrating structure, process, and outcome data within a unified national project aligns SOCAS with international best practices in perioperative quality monitoring. This integration also supports the project's relevance for clinical, academic, and policy stakeholders.

3. Objectives / Aims

Primary Aim

To assess perioperative morbidity and mortality in patients undergoing anesthesia in Switzerland, using standardized, prospectively collected data within the framework of a national quality initiative.

Primary Objective

- To determine all-cause mortality rates at hospital discharge and 180 days following anaesthesia.

Secondary Objectives

A. Complications and Clinical Outcomes

- To quantify perioperative morbidity using standardized classification systems:
  - Intraoperative complications (ClassIntra scale)
  - Postoperative complications within 24 hours (A-QUA 24h)
  - Postoperative complications during hospital stay (Clavien-Dindo classification)
  - Incidence of postoperative delirium

B. Risk Factor Analysis

- To identify associations between perioperative outcomes and:
  - Patient-related variables, including age, sex, ASA classification, and comorbidities
  - Procedure-related factors, including surgical type, urgency (elective/ emergency), and complexity
  - Anaesthesia-related characteristics, such as technique, monitoring standards, and team composition

C. Institutional Comparisons

- To evaluate variation in perioperative outcomes across participating institutions
- To explore differences between A-CERT-certified and non-certified centers with regard to complication rates and quality indicators

D. Resource Utilisation

- To assess:
  - Duration of stay in ICU
  - Total hospital length of stay (LOS)

E. Quality System Integration

- To demonstrate the feasibility and utility of combining:
  - Routine clinical outcome data (A-QUA)
  - Organizational quality audit findings (A-CERT)

- To support the development of a scalable national perioperative quality surveillance and feedback system

Hypotheses

1. Perioperative outcome levels in Switzerland are comparable to other high-income countries and reflect international benchmarks.
2. Risk-adjusted variation exists between institutions, influenced by clinical practices, infrastructure, and team configuration.
3. Certified institutions (A-CERT) demonstrate improved adherence to standards and lower adverse event rates compared to non-certified centers.
4. Patient characteristics, including sex and age, influence the incidence and severity of complications.
5. Anaesthesia modality and intraoperative management factors are associated with outcome variability.

4. Study Design and Methods

4.1 Study Design

SOCAS is a prospective, multicenter, observational quality project conducted across Swiss anesthesia institutions. This non-interventional project is embedded within routine clinical workflows. The project aims to collect perioperative outcome data using standardized instruments without altering patient management or introducing experimental procedures.

SOCAS is implemented within the existing framework of:

- A-QUA, the national anaesthesia quality data platform
- A-CERT, the peer-reviewed institutional certification program

The project is designed to assess real-world outcomes and institutional performance across a representative sample of Swiss hospitals.

4.2 Setting

Participating sites are anaesthesia departments that:

- Contribute to the A-QUA program
- Are certified or eligible for certification through A-CERT

At least 10 institutions will participate, representing a range of geographic locations, sizes, surgical caseloads, and institutional structures.

4.3 Duration

- Study period: 3–6 months of data collection, depending on site capacity
- Follow-up period: 180 days post-procedure
- Total project duration: 24-36 months (including planning, ethics approval, data analysis, and reporting)

4.4 Study Population

4.4.1 Target Population

All patients who received anesthesia, with or without surgery, at participating institutions during the study period are included in the analysis.

4.4.2 Inclusion Criteria

- Consecutive patients receiving anesthesia
- Treated in departments participating in the A-QUA program

4.4.3 Exclusion Criteria

- None. The project is designed to capture an unselected, real-world perioperative population.

4.5 Outcomes and Measurements

Data will be captured using predefined fields in A-QUA, supplemented by SOCAS-specific variables. Outcomes include:

- **Mortality**
  - In-hospital mortality
  - 180-day all-cause mortality
- **Complications**
  - Intraoperative events (ClassIntra)
  - Postoperative complications within 24 hours (A-QUA 24h)
  - In-hospital complications (Clavien-Dindo)
  - Postoperative delirium
- **Resource Use**
  - ICU length of stay
  - Total hospital LOS

4.6 Data Management

- Data entry is performed as part of routine clinical documentation
- All entries are pseudonymized at the point of documentation
- Data are securely stored in the national A-QUA database
- Data quality is assured via:
  - Automated consistency checks
  - Central monitoring by the SOCAS data team
  - Site-level oversight by trained coordinators

4.7 Ethical and Regulatory Compliance

As a non-interventional project that uses routine, pseudonymized data, SOCAS is subject to quality assurance activities, as defined by Swiss law (HFG Art. 34 / HFV). Nevertheless, the protocol will be submitted to the Ethics Committee of the Canton of Zurich (KEK Zurich) for confirmation and oversight.

Most institutions already operate under a general patient consent model, permitting the secondary use of pseudonymized clinical data for quality improvement and research.

4.8 Feasibility and Site Engagement

The infrastructure necessary for SOCAS has already been established:

- A-QUA is implemented in participating institutions
- A-CERT ensures readiness in certified sites
- Local quality officers or study nurses will support implementation and follow-up

Based on institutional procedure volumes (~4,000 anaesthetic cases/3 months), the target sample size (~40,000 cases) is feasible within the anticipated study window.

5. Outcomes

5.1 Primary Outcome

- All-cause mortality
  - Assessed at two timepoints:
    - In-hospital (up to discharge)
    - At 180 days post-procedure

These endpoints are chosen to reflect both early and intermediate postoperative risk, and to align with international standards in outcome reporting.

5.2 Secondary Outcomes

The following secondary outcomes will be assessed using standardized instruments:

A. Intraoperative and Postoperative Complications

- Intraoperative events classified using the ClassIntra scale
- Postoperative complications within 24 hours, as documented in A-QUA 24h
- Postoperative complications during hospitalization, using the Clavien-Dindo classification
- Incidence of in-hospital postoperative delirium, as identified through routine clinical screening and A-QUA documentation

B. Resource Use and Recovery

- Length of stay (LOS) in:
  - Intensive Care Unit (ICU)
  - Overall hospital stay

5.3 Derived Quality Indicators (for benchmarking and feedback)

Based on the above data, SOCAS will support the development of composite and stratified indicators such as:

- Risk-adjusted complication rates
- Mortality-to-complication ratio
- Institution-specific outcome profiles
- Sex-specific and age-stratified outcome patterns
- Outcome differences between A-CERT certified and non-certified institutions

These indicators will be used for descriptive benchmarking, hypothesis generation, and internal quality improvement purposes.

5.4 Measurement Tools and Definitions

- ClassIntra: A validated classification system for grading the severity of intraoperative events

- A-QUA 24h: Structured documentation of complications occurring in the first postoperative day
- Clavien-Dindo: A widely adopted scale for postoperative complications, ranging from minor to life-threatening events
- Delirium: Defined according to institutional screening protocols (e.g., CAM, Nu-DESC) and recorded in A-QUA fields

6. Sample Size, Power, and Study Period Definition

6.1 Target Sample Size

SOCAS aims to enroll approximately 40,000 consecutive patients undergoing anesthesia (with or without surgery) across at least ten Swiss institutions. This sample size has been selected in order to:

- Provide precise national estimates of key perioperative outcomes
- Enable risk-adjusted, stratified, and multivariable analyses
- Ensure feasibility within a 3–6-month data collection period, assuming each center contributes ~4,000 cases

6.2 Expected Event Rates and Statistical Power

Based on Swiss and international benchmarks, the following event rates and case numbers are expected:

Outcome	Estimated Rate	Projected Events N = 40,000
In-hospital mortality	1–2%	400–800
180-day mortality	2–3%	800–1,200
Severe complications (anaesthesia-related)	0.5%	200
Moderate complications	10%	4,000
Mild complications	20%	8,000
Postoperative delirium	5–15%	2,000–6,000

The frequency of this event supports multivariable logistic regression and subgroup analysis with acceptable precision. This satisfies the ≥10 events per variable (EPV) requirement for risk adjustment.

6.3 Statistical Precision and Center Variation

Precision of outcome estimates depends on each center's sample size. For example:

Center Sample Size	Expected Deaths (1.5%)	95% CI for Mortality (%)	CI Width (%)
1,000	15	0.75–2.25	1.51
2,000	30	0.97–2.03	1.07
4,000	60	1.12–1.88	0.75
5,000	75	1.16–1.84	0.67

Smaller centers (those with fewer than 2,000 patients) yield wide confidence intervals, which limits the interpretability of center-specific mortality estimates. This variation must be considered when developing a benchmarking strategy.

6.4 Analytical Approach to Center Variation

To address variability across sites and ensure statistically valid comparisons, the following strategies will be employed:

- Primary analyses will be performed at the pooled national level
- Multilevel (hierarchical) modelling will account for clustering within centers
- Empirical Bayes estimates may be used to stabilize center-level outcome metrics, especially for rare events
- Center-level comparisons will only be reported if minimum volume thresholds are met (e.g., ≥2,000 patients)

6.5 Definition of Study Period and Cohort Strategy

A consistent and well-structured inclusion strategy is essential for comparability and feasibility. Several options have been evaluated:

Option 1: Fixed Calendar Window

- All centers collect data during the same 3-month period (e.g., October–December 2026)
- Pros: Simultaneity; seasonal consistency
- Cons: Risk of site delays or incomplete data

Option 2: Rolling Inclusion Period (per center)

- Each center selects its own start date and contribute a defined number of patients
- Pros: Flexibility: Accommodates staggered startup
- Cons: Less temporal alignment; potential confounding by time

Option 3: Cohort-Based Design

- All centers include cases in recurring, defined time blocks (e.g., first week of each month)
- Pros: Enables time-stratified analysis; consistent effort over time
- Cons: Operationally complex; smaller per-cohort sample sizes

6.6 Recommended Cohort Execution Plan

To balance feasibility, precision, and comparability, SOCAS proposes the following:

- **Each center will contribute a consecutive cohort**
  - Centers select a defined start date between Q2 2026 and Q3 2026
  - Contribution > 2'000 patients
  - Data collection must be continuous and uninterrupted
- **Follow-up at 180 days** will be completed for all patients
- A central schedule will coordinate overlapping data periods to ensure representative coverage
- If multiple centers report lower-than-expected volumes, **up to 12–14 centers** may be recruited to maintain the total sample size and analytic power

This approach ensures:

- Temporal consistency without rigid simultaneity
- Minimal disruption to local operations
- Reliable risk-adjusted comparisons and pooled estimates

6.7 Stakeholder Discussion Points

To finalize the study protocol, participating centers and sponsors should discuss the following jointly:

- Preferred inclusion window and start date coordination
- Capacity to contribute ≥4,000 patients over 3 months
- Willingness to extend the collection period or join as additional sites if needed
- Acceptable thresholds for inclusion in institutional comparisons

The final study calendar and center roster will be established following confirmation of site readiness and ethics approval.

7. Statistical Analysis

7.1 General Approach

The analyses in this study will serve dual purposes. Firstly, they will be descriptive and exploratory**,** aimed at providing a comprehensive overview of current practices and outcomes, thereby supporting benchmarking and ongoing quality monitoring across institutions. Secondly, the analyses will have an inferential component, designed to identify and evaluate potential causal and associative relationships between various patient, procedural, and institutional factors and perioperative outcomes. This dual approach ensures both a detailed understanding of the current state and a data-driven foundation for future improvements in perioperative care.

7.2 Data Handling and Quality Control

- **Data Sources**: A-QUA national database, supplemented with variables from SOCAS (Swiss national anaesthesia registry).
- **Data Characteristics**: Pseudonymized patient-level data with unique institution-level identifiers.
- **Quality Assurance Measures**:
    - Automated validation (logical checks, range checks, duplicate detection).
    - Manual review of key variables and outcomes for consistency and completeness.
    - Application of exclusion criteria for implausible or incomplete entries based on predefined algorithms.
    - Maintenance of a comprehensive data dictionary and variable coding reference.

7.3 Descriptive Analyses

- Categorical variables presented as counts and percentages.
- Continuous variables reported as mean (standard deviation) or median (interquartile range), depending on distribution.
- **Subgroup Analyses**: Summary statistics will be stratified by:
    - Institution
    - Anaesthesia type
    - Procedure class
    - Risk strata (e.g., ASA, age group, sex)

7.4 Outcome Analysis

Primary Endpoint

- All-cause mortality:
    - At hospital discharge and at 180-day post-anaesthesia.
    - Crude and adjusted rates will be reported at the national and center level.
    - Kaplan-Meier survival curves may be generated for time-to-event visualization.

Secondary Endpoints

- Intraoperative events (ClassIntra)
- Postoperative complications (A-QUA 24h, Clavien-Dindo)
- Postoperative delirium
- Length of stay (PACU, IMC, ICU, total)

Each endpoint will be analyzed for:

- Incidence rates will be calculated overall and per center
- Confidence intervals will be provided
- Stratified reporting will include patient characteristics (age, sex, ASA classification), anaesthesia technique, and surgical risk

7.5 Multivariable Modelling

To identify independent predictors of adverse outcomes:

- **Binary outcomes** (e.g., mortality, delirium): Logistic regression.
- **Ordinal outcomes** (e.g., Clavien-Dindo grades): Ordinal logistic regression or multinomial models.
- **Continuous outcomes** (e.g., length of stay): Linear regression or quantile regression as appropriate.
- **Time-to-event outcomes** (e.g., 180-day survival): Cox proportional hazards regression, provided accurate date data is available.

Candidate Covariates:

- Age, sex, ASA class, comorbidities
- Type and urgency of procedure
- Anaesthesia technique
- Institutional variables (A-CERT certification status, annual caseload)

Model performance will be evaluated using:

- Goodness-of-fit tests
- Area under the curve (for logistic models)
- Proportional hazards assumptions (for survival models)

7.6 Center-Level Comparisons and Hierarchical Modelling

- **Multilevel modeling**: Patients nested within institutions
- **Random-intercept models**: To estimate institution-specific baseline risk
- **Empirical Bayes estimation**: To reduce noise in low-volume center estimates
- **Minimum threshold**: Centers must contribute at least 2,000 cases with complete data to be included in institutional comparisons
- **Governance**: Institutional findings will be reviewed by the study steering committee before dissemination

Reporting of institutional results will be conditional on:

- Minimum N per center (e.g., ≥2,000)
- Sufficient data completeness
- Internal review by the study steering committee

7.7 Handling of Missing Data

- Exploratory analysis: To characterize missingness patterns
- Primary analysis: Complete-case dataset
- Sensitivity analysis: Multiple imputation for missing predictors if >5–10% missingness observed
- Imputation model: Will include outcome and auxiliary variables to satisfy the missing at random (MAR) assumption

7.8 Software and Reproducibility

All analyses will be conducted using R or Stata, with full reproducibility ensured via version-controlled code. The analysis plan will be finalized before data lock and archived with the study documents.

8. Ethical and Regulatory Considerations

8.1 Legal Classification and Risk Level

The SOCAS project is a non-interventional quality initiative that uses pseudonymized routine clinical data collected as part of the national A-QUA program. According to Swiss law, it is classified as a quality assurance activity (Qualitätssicherungsprojekt).

- Federal Human Research Act (HFG), Article 34
- Human Research Ordinance (HFV), particularly Articles 2 and 3

As such, the project is expected to fall under the category of non-HF research. There should be no added risk to patients, and individual patient consent should not be necessary if general consent is in place.

8.2 Ethical Review Procedure

Despite its low-risk classification, the project will be submitted to the Kantonale Ethik-kommission Zürich (KEK Zurich), the lead ethics committee, for review under the BASEC framework in a multicenter procedure.

Ethics approval will be requested for:

- Use of pseudonymized patient data derived from routine care
- Institutional benchmarking and quality reporting
- 180-day follow-up using hospital records or registry data, where feasible

Participating institutions will be included through the multicantonal approval process, with local confirmations if required.

8.3 Patient Consent

In line with Swiss ethical guidance and legal provisions:

- No individual patient consent is required for the use of fully pseudonymized quality data
- Most participating hospitals already operate under a general informed consent framework, which includes secondary use of clinical data for quality and research purposes
- The SOCAS protocol and ethics application will include:
    - Confirmation of pseudonymization at the point of data entry (A-QUA system)
    - No patient-identifying variables exported centrally
    - No intervention or deviation from standard clinical care

For any center lacking general consent infrastructure, data will be excluded from use unless local ethics approval permits it under a comparable framework.

8.4 Data Protection and Privacy

All data collected for SOCAS will be handled in accordance with Swiss data protection regulations:

- Pseudonymization will occur at the institutional level
- No personal identifiers (name, date of birth, insurance ID, etc.) will be stored in the central study database
- Data will be transmitted and stored using encrypted, access-controlled systems
- Access will be limited to authorized members of the SOCAS data management and analysis team

8.5 Oversight and Compliance

The ethical and legal compliance of the study will be monitored by:

- The SOCAS steering committee, which includes representation from the sponsor (SPSA), participating institutions, and ethics experts
- The lead ethics committee (KEK Zurich) through formal correspondence and amendments
- Each participating site's designated study lead or ethics liaison

Should any changes to protocol scope, data use, or inclusion criteria arise, a formal amendment will be submitted to the lead ethics committee and, if required, to all involved sites.

9. Project Timeline

The implementation of SOCAS will follow a coordinated, staged approach to ensure regulatory compliance, institutional readiness, high-quality data collection, and timely analysis. The project is estimated to last 24 months, beginning with sponsor and ethics preparation in Q3 2025 and concluding with publication in Q3–Q4 2027.

9.1 Key Milestones

Phase	Activity	Timeline
Preparation Phase	Final protocol approval, sponsor confirmation, ethics drafting	Q3 2025
Ethics Submission	Submission to KEK Zurich (lead); multicantonal BASEC coordination	Q3–Q4 2025
Site Agreements	Site selection, onboarding, training, and cohort date definition	Q4 2025
Data Collection Period	3-month inclusion window per center (rolling start permitted)	Q1–Q2 2026
Follow-Up Completion	180-day outcome tracking for all included patients	Q3 2026–Q1 2027
Data Cleaning and Analysis	Final data validation, statistical modelling, benchmarking	Q1–Q2 2027
Dissemination	Institutional reports, sponsor briefings, scientific publication	Q3–Q4 2027

9.2 Center-Specific Scheduling

Each participating center will:

- Define a consecutive 3-month inclusion period
- Begin data collection no later than Q2 2026
- Ensure documentation of follow-up until 180 days post-procedure

The central coordination team will monitor enrollment progress, support data completeness, and maintain a shared project calendar for transparency.

9.3 Contingency Planning

To maintain timeline integrity:

- Centers unable to meet onboarding deadlines may be substituted
- Additional sites (beyond the initial 10–12) may be invited if volume shortfalls are identified
- Ethics amendments (e.g., for timeline extensions) will be submitted as needed

10. Study Implementation, Sponsorship, and Governance

10.1 Governance Structure

The SOCAS project is conducted under the scientific leadership of the SOCAS Study Group on behalf of the Stiftung für Patientensicherheit in der Anästhesie (SPSA) and with strategic support from the Swiss Society for Anesthesiology and Perioperative Medicine (SSAPM). A steering committee comprising senior representatives from participating institutions and advisory experts in perioperative outcomes research provides oversight.

The project is coordinated centrally, with defined responsibilities for:

- Scientific direction: SOCAS Study Group (CKH, MTG)
- Project sponsorship: SPSA, with additional support (see 10.3)
- Operational coordination: Central project office and local site leads

10.2 Ethics and Regulatory Oversight

In accordance with Swiss regulations for multicenter projects, SOCAS will be submitted for review to the lead ethics committee, the Kantonale Ethikkommission Zürich (KEK Zurich). The project is classified as a non-interventional, low-risk quality initiative under HFG Art. 34 and HFV.

Key considerations include:

- Use of pseudonymized routine care data, without active intervention
- Most participating hospitals already operate under a general consent framework
- Multicantonal approval will be sought with central coordination of additional local ethics requirements

Ethics submission will be led by the chief investigators and prepared with standardized templates for all sites.

10.3 Sponsorship and Institutional Support

In addition to the SPSA, SOCAS will seek partnership and endorsement from national stakeholders in healthcare including:

- FMCH (Foederatio Medicorum Chirurgicorum Helveticorum)
- H+ Die Spitäler der Schweiz
- SASIS AG (analytics division of santésuisse)
- Stiftung für Patientensicherheit
- Selected insurance partners

Sponsors will be engaged to support:

- Financial contributions (study nurse FTEs, central coordination)
- Institutional promotion and recruitment support
- Integration with national quality strategies

10.4 Site Participation and Onboarding

Participating institutions must:

- Be active contributors to the A-QUA program
- Appoint a local study lead and contact person
- Provide a minimum 3-month continuous data collection period

Preferably, sites should also be A-CERT certified or in the process of certification. A total of 10–14 centers will be recruited to ensure target sample size and geographic balance.

Each site will receive:

- Study protocol and documentation templates
- Ethics submission support
- Secure access to the SOCAS data framework
- Training material for local data coordinators

10.5 Timeline and Milestones

Phase	Activity	Period
Preparation	Finalize protocol, ethics documents, sponsor engagement	Q3 2025
Ethics submission	KEK Zurich (lead), multicantonal approval via BASEC	Q3–Q4 2025
Site onboarding	Site agreements, coordinator training	Q4 2025
Data collection	3-month inclusion period per center	Q1–Q2 2026
Follow-up period	180-day outcomes collection	Q2–Q3 2026
Analysis & reporting	Data cleaning, modelling, feedback reports	Q4 2026

Upon onboarding, sites will define their inclusion window to allow for a staggered start-up. A centralized registry will be maintained for timeline tracking.

11. Funding Strategy

11.1 Strategic Institutional Sponsors

These organizations represent the primary system-level stakeholders for SOCAS. Their involvement ensures professional, institutional, and political alignment with national quality improvement goals:

Organization	Role in SOCAS	Relevance
FMCH (Foederatio Medicorum Chirurgicorum Helveticorum)	Co-sponsorship, funding, policy advocacy	Umbrella organization for Swiss surgical societies; supports multidisciplinary perioperative initiatives
H+ Die Spitäler der Schweiz	Sector-wide engagement and co-financing	Represents public and private hospitals; critical partner for institutional rollout
SSAPM (Swiss Society for Anaesthesiology and Perioperative Medicine)	Professional leadership, scientific support	Founding partner of A-QUA and A-CERT; essential for communication and professional endorsement
SPSA (Stiftung für Patientensicherheit in der Anästhesie)	Lead sponsor, operational oversight	Coordinates implementation, data governance, and stakeholder integration
Santésuisse / Curafutura	Health insurance umbrella organizations	May support benchmarking or registry integration through SASIS AG

11.2 Federal and Public Health Agencies

SOCAS aligns with national priorities in healthcare, including quality, transparency, and value-based delivery. Public institutions that may offer project funding, endorsement, or collaboration include:

Institution	Pathway
BAG (Bundesamt für Gesundheit)	National Quality Strategy (Nationale Qualitätsentwicklung, NQE); direct grants for pilot and model projects
Schweizerische Qualitätskommission (SQK)	Funding or evaluation support for system-wide quality initiatives
Health Observatory (Obsan)	Data cooperation or shared metrics
Swiss Personalized Health Network (SPHN)	Interoperability and data standards (A-QUA/SPHN alignment)

11.3 Foundations and Non-Profit Organizations

A wide range of Swiss foundations support public health, safety, innovation, and data-based decision-making. Based on SOCAS scope, priority targets include:

Foundation	Focus Area	Relevance
Stiftung Gesundheitsförderung Schweiz	Quality of care, system prevention	Clear alignment with perioperative outcome transparency
Gebert Rüf Stiftung	Public sector innovation, pilot projects	Supports system-improving tools and interdisciplinary collaboration
Beisheim Stiftung	Healthcare system transformation, ageing	Strong match with outcomes and delirium focus
Paul Schiller Stiftung	Health and dignity in ageing	May support delirium and geriatric anaesthesia focus
Symphasis Stiftung	Medical research with system benefit	Alignment with registry-based outcome improvement
Anna-Müller Grocholski Stiftung	Equity and social responsibility in medicine	Relevance for sex-specific and risk stratification analysis
Stiftung Sanitas Krankenversicherung	Health promotion and digital tools	Focus on outcome transparency and patient empowerment
Stiftung Gesundheitsversorgung Zürich	Regional quality improvement	Potential linkage to KEK Zurich and cantonal alignment
Jacobs Foundation	Evidence-based systems change	May engage for data-sharing and impact dissemination models
Novartis Stiftung für Medizinisch-Biologische Forschung	Research in health data sciences	Option for analytical component support (secondary analyses)

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Appendix A. Organizational Structure and Roles

Project Title

SOCAS – Swiss Outcome After Anaesthesia and Surgery

A.1 Chief Investigators

Name	Institution	Role
Prof. Dr. Michael T. Ganter	Klinik Hirslanden Zürich	Chief Investigator
Prof. Dr. Christoph K. Hofer	Schulthess Klinik Zürich	Chief Investigator

A.2 Project Sponsor

Stiftung für Patientensicherheit in der Anästhesie (SPSA)

- Legal sponsor under Swiss ethics law
- Provides oversight, coordination, and governance
- Contact: SPSA Secretariat, Zürich

A.3 Study Group (SOCAS Study Group)

Responsible for protocol development, scientific integrity, and operational planning.

- Prof. Dr. Christoph Hofer (Schulthess Klinik Zürich)
- Prof. Dr. Michael Ganter (Hirslanden Zürich)
- Prof. Dr. Thierry Girard (Universitätsspital Basel)
- Prof. Dr. Urs Eichenberger (Universitätsklinik Balgrist)
- PD Dr. Caveh Madjpur (Kantonsspital Winterthur)
- Dr. Asimina Lazaridou (Schulthess Klinik)

A.4 Advisory Board

Provides strategic oversight and scientific guidance.

- Prof. Dr. Rupert M. Pearse (Queen Mary University of London)
- Prof. Dr. Beatrice Beck Schimmer (Universität Zürich)
- Andrea Rytz (CEO, Schulthess Klinik Zürich)

A.5 Local Study Leads (Per Center)

Each participating site will designate a local principal investigator (PI) and study coordinator responsible for:

- Ethics compliance
- Data completeness and pseudonymization
- Local team training and logistics

Appendix B. Data Collection Framework (A-QUA Variables Used in SOCAS)

The SOCAS study uses a defined subset of the national A-QUA dataset, supplemented with additional fields for follow-up and outcome stratification.

B.1 Data Domains from A-QUA 1 & 2

Domain	Example Variables
Patient Risk Profile	Age, sex, BMI, ASA class, comorbidities
Procedure Information	Surgical code, urgency (elective/emergency), duration
Anaesthesia Technique	General/regional/combined, airway management
Intraoperative Events	ClassIntra classification, medication events
Immediate Postop	A-QUA 24h complications, PACU stay, ICU admission
Outcome Indicators	In-hospital complications (Clavien-Dindo), delirium

B.2 SOCAS-Specific Variables (Supplemented Fields)

Variable	Collection Point
Length of hospital stay (total)	At discharge
In-hospital delirium	During stay (clinical screening)
In-hospital mortality	At discharge
180-day mortality (yes/no, date)	Via follow-up data query

Data will be collected using the existing A-QUA platform, with no changes to clinical routines. Additional fields are configured through local EDP systems and harmonized for central analysis.

Appendix C. Definitions of Outcome Measures

The SOCAS study uses validated and standardized classifications for all perioperative complications and endpoints to ensure data comparability across institutions and alignment with international quality frameworks.

C.1 Primary Outcome: Mortality

Outcome	Definition
In-hospital mortality	Death occurring during the index hospital stay after anaesthesia
180-day all-cause mortality	Death from any cause within 180 days of the index anaesthesia procedure

Mortality data will be collected from institutional medical records or routine follow-up systems in participating hospitals.

C.2 Intraoperative Events – ClassIntra

SOCAS uses the ClassIntra scale, a validated grading system for intraoperative adverse events (AEs), developed in collaboration with the ISOS group.

Class	Definition
0	No deviation from ideal intraoperative course
I	Minor deviation requiring only observation or minimal treatment
II	Moderate deviation requiring increased monitoring or medication without long-term sequelae
III	Major deviation potentially affecting outcome or prolonging surgery
IV	Severe event with potential for significant patient harm or conversion of anaesthesia plan
V	Intraoperative death

Data are recorded by the anaesthesia team at the end of the procedure and integrated into A-QUA documentation.

C.3 Postoperative Complications – A-QUA 24h

Early postoperative events are defined as any clinical complication or deviation from the expected recovery course within the first 24 hours following anaesthesia.

Common A-QUA 24h indicators include:

- Hypotension requiring intervention
- Respiratory distress or desaturation

- Nausea/vomiting requiring antiemetics
- Reintubation or ICU transfer
- Unexpected bleeding or return to OR

These are recorded using predefined structured fields in the A-QUA system.

C.4 Postoperative Complications – Clavien-Dindo Classification

Overall perioperative complication burden during hospitalization is categorized using the Clavien-Dindo system:

Grade	Definition
I	Deviation from normal postoperative course without pharmacological, surgical, or endoscopic intervention
II	Requiring pharmacological treatment (excluding minor drugs)
IIIa	Requiring surgical, endoscopic, or radiological intervention without general anaesthesia
IIIb	Requiring intervention under general anaesthesia
IVa	Life-threatening complication requiring ICU management
IVb	Multi-organ failure
V	Death

Classification is based on discharge summaries and in-hospital clinical course.

C.5 Postoperative Delirium

Defined as an acute disturbance in attention, awareness, and cognition occurring during the hospital stay, and assessed using validated screening tools (as implemented at each center), including:

- CAM (Confusion Assessment Method)
- Nu-DESC (Nursing Delirium Screening Scale)
- DSM-5 criteria (if documented by medical staff)

Data are extracted from standard clinical documentation or A-QUA outcome fields.

Appendix D. Ethics and Consent Framework

D.1 Legal and Ethical Basis

The SOCAS project is conducted in accordance with the following Swiss legislation:

- Federal Act on Research Involving Human Beings (Humanforschungsgesetz, HFG), Article 34
- Human Research Ordinance (HFV), Articles 2–3
- Swiss Data Protection Act (DSG)

Based on these provisions, SOCAS qualifies as a non-interventional quality assurance project, as it:

- Uses pseudonymized data
- Collecting data as part of routine care
- Does not intervene in patient management
- Poses no additional risk to participants

D.2 Ethics Submission and Review Process

- The project will be submitted to KEK Zurich as the lead ethics committee
- Multicantonal coordination will be conducted via BASEC (Business Administration System for Ethics Committees)
- All participating sites will be included in the primary submission
- If required, local sites may provide institutional confirmation letters

D.3 Consent Requirements

Under HFG Art. 34 and HFV, individual patient consent is not required if:

- Data are fully pseudonymized
- Collected exclusively as part of routine care
- Used for quality improvement or research purposes compatible with general consent policies

SOCAS fulfills all these conditions.

Furthermore, the majority of participating institutions operate under General Informed Consent procedures that explicitly allow use of routine clinical data for quality monitoring and observational research.

Documentation for each center's general consent policy will be retained for ethics records.

D.4 Pseudonymization and Data Protection

Aspect	Procedure
Pseudonymization	Done at the local center before data export; no patient identifiers transferred
Identifiers excluded	Name, date of birth, insurance ID, and other direct identifiers
Data security	Transmission via encrypted systems; central A-QUA storage with access restrictions
Access control	Limited to named SOCAS investigators, data managers, and monitors
Audit trail	All data handling activities will be logged

No re-identification is planned or possible within the study framework.

D.5 Participant Communication (Optional)

Although consent is not required, centers may choose to:

- Inform patients about the project through public information posters or website announcements
- Reference SOCAS in their general hospital data protection policies

A sample one-page patient information flyer (optional) can be developed if requested by sites or KEK Zurich.

Appendix E. Site Participation Agreement (Template)

Teilnahmevereinbarung (Vorlage)

Swiss Outcome After Anaesthesia and Surgery – SOCAS

1. Vertragspartner

Diese Vereinbarung wird geschlossen zwischen:

- **Sponsor**:
  Stiftung für Patientensicherheit in der Anästhesie (SPSA)
  Vertreten durch die SOCAS-Studiengruppe
  [Adresse der SPSA / Geschäftsstelle]
- **Teilnehmende Institution**:
  [Name des Spitals / der Institution]
  [Klinik für Anästhesiologie / Qualitätsmanagement]
  Vertreten durch: [Lokale Studienleitung / Klinikleitung]

2. Zweck der Vereinbarung

Diese Vereinbarung regelt die Verantwortlichkeiten und die Zusammenarbeit im Rahmen der Teilnahme an SOCAS, einer prospektiven, multizentrischen, nicht-interventionellen Qualitätsinitiative zur Erhebung der perioperativen Morbidität und Mortalität in der Schweiz.

3. Umfang der Teilnahme

Die teilnehmende Institution verpflichtet sich:

- Alle konsekutiven, eingeschlossenen Patient:innen während eines definierten 3-monatigen Erhebungszeitraums zu dokumentieren
- Die vollständige Datenerfassung gemäss SOCAS-Protokoll über die A-QUA-Plattform sicherzustellen
- Die Pseudonymisierung aller exportierten Daten auf lokaler Ebene vorzunehmen
- Die Dokumentation von 180-Tage-Follow-up-Daten (v. a. Mortalität) zu ermöglichen
- Eine:n lokale:n Studienverantwortliche:n zu benennen, der/die als Kontaktperson zur Studienzentrale fungiert

Die SPSA verpflichtet sich:

- Das vollständige Studienprotokoll, Ethikunterlagen und Dokumentenvorlagen bereitzustellen
- Die Einreichung bei der KEK Zürich und über BASEC zentral zu koordinieren
- Studienmaterialien, Rückmeldungen und statistische Auswertungen bereitzustellen
- Die Einhaltung aller geltenden Datenschutzbestimmungen zu gewährleisten

4. Ethik und rechtlicher Rahmen

- Die Studie wird als multizentrales Qualitätssicherungsprojekt bei der KEK Zürich eingereicht

- Eine individuelle Einwilligung der Patient:innen ist gemäss HFG Art. 34 nicht erforderlich, sofern die Daten pseudonymisiert sind
- Die Institution bestätigt, dass eine Generaleinwilligung (sofern vorhanden) die Nutzung für Qualitätsprojekte abdeckt

5. Datennutzung und Berichterstattung

- Die Datenhoheit verbleibt bei der jeweiligen Institution
- Aggregierte und anonymisierte Daten dürfen verwendet werden für:
  - Wissenschaftliche Publikationen
  - Benchmark-Berichte für teilnehmende Zentren
  - Strategieberichte für nationale Akteure
- Eine namentliche Nennung der Institution erfolgt nur nach schriftlicher Zustimmung

6. Finanzielle und operationelle Bestimmungen

Diese Vereinbarung stellt keinen kommerziellen Vertrag dar. Eventuelle finanzielle Beiträge (z. B. zur Finanzierung einer Studienassistenz) werden in separaten Vereinbarungen geregelt.

7. Gültigkeit und Beendigung

Diese Vereinbarung tritt mit Unterzeichnung in Kraft und gilt bis:

- Der Abschluss und die Auswertung des Projekts oder
- Eine einvernehmliche oder begründete Kündigung erfolgt (z. B. bei Nichteinhaltung)

8. Unterschriften

Sponsor – Stiftung für Patientensicherheit in der Anästhesie (SPSA)
Name: .....
Unterschrift: .....
Datum: .....

Teilnehmende Institution
Name: .....
Funktion: .....
Unterschrift: .....
Datum: .....

Appendix F. Budget Overview

F.1 Funding Strategy

The financing of the SOCAS project is based on a mixed funding model, including contributions from:

- National professional organizations and sponsors (e.g. SPSA, SSAPM, FMCH, H+)
- Public agencies (e.g. BAG, foundations)
- Participating institutions (co-financing, depending on capacity)

The budget exclusively covers quality-related activities (data collection, coordination, statistical analysis). The project does not include interventional procedures or study-specific patient care.

F.2 Budget Components

Category	Description	Estimated Cost (CHF)
1. Central Project Coordination	Project management, ethics coordination, communication	60,000.–
2. Data Management & IT	Data quality control, monitoring, A-QUA integration	40,000.–
3. Statistical Analysis	Modelling, benchmarking, visualisation	50,000.–
4. Site-Level Personnel	Study nurse or coordinator per site (0.2–0.5 FTE, 3–5 months)	6,600.–/month/site
5. Total Site Costs	Approx. 33,000.– per site over 5 months	330,000.– (10 sites)
6. Follow-up & Quality Control	180-day data validation and support	20,000.–
7. Dissemination & Reporting	Institutional feedback, publication, workshops	15,000.–

F.3 Total Budget Estimate (for 10 Centers)

Category	Amount (CHF)
Central Coordination & Analysis	185,000.–
Site-Level Costs (10 centers)	330,000.–
Total Project Budget	**~515,000.–**

If more than 10 centers participate, or if the data collection period is extended, the budget must be adjusted accordingly.

F.4 Proposed Funding Distribution

Contributor	Target Share
SPSA / SSAPM (seed funding)	20–25 %
Public funding (e.g. BAG, foundations)	30–40 %
Institutional contributions (per site)	30–40 %
In-kind support (IT, admin)	Included

F.5 Budget Use and Accountability

- Sites may receive a coordination allowance or use funds to hire internal support staff
- No commercial or industry sponsorship is foreseen for this phase
- Financial oversight and reporting will be managed centrally by the sponsor (SPSA), in line with project governance and transparency principles

Appendix G. Statistical Tables and Power Analysis Outputs

This appendix provides additional data from power calculations and center-level precision analysis. These estimates are based on projected event rates for a total study population of 40,000 patients, stratified by outcome frequency and center size.

G.1 Estimated Outcome Events (N = 40,000)

Outcome	Estimated Rate	Expected Events
In-hospital mortality	1.5%	600
180-day mortality	2.5%	1,000
Severe anaesthesia-related complications	0.5%	200
Moderate complications	10%	4,000
Minor complications	20%	8,000
Postoperative delirium (range)	5–15%	2,000–6,000

These frequencies provide sufficient statistical power for national estimation and multivariable regression modeling.

G.2 Confidence Interval Precision for Mortality by Center Size

Assuming a 1.5% mortality rate, the table below shows the width of 95% confidence intervals for centers of different sizes:

Center Sample Size	Expected Deaths	95% CI Lower (%)	95% CI Upper (%)	CI Width (%)
1,000	15	0.75	2.25	1.50
2,000	30	0.97	2.03	1.06
3,000	45	1.07	1.93	0.86
4,000	60	1.12	1.88	0.76
5,000	75	1.16	1.84	0.68

Centers enrolling fewer than 2,000 patients will have wider CIs, limiting interpretability of site-specific mortality rates.

G.3 Regression Modeling Feasibility

With 600–1,000 deaths and several thousand complication events, the following modeling strategies are feasible:

Model Type	Outcome	Estimated EPV Support
Logistic regression	In-hospital and 180-day mortality	20–30 covariates
Ordinal regression	Clavien-Dindo complication severity	15–25 covariates
Linear regression	Length of stay (LOS)	≥30 predictors
Multilevel logistic regression	Center-adjusted outcomes	By nesting patients within institutions

EPV = Events per Variable (rule of thumb ≥10)

G.4 Benchmarking Readiness Criteria

To ensure robust comparisons across centers:

- Minimum case threshold for center-level benchmarking: ≥2,000 patients
- Sufficient event frequency (e.g., ≥20 deaths or ≥100 complications)
- Complete follow-up for ≥95% of included patients

Centers not meeting these criteria will be included in pooled analyses but excluded from standalone institutional benchmarking reports.

Appendix H. Dissemination and Reporting Plan

The SOCAS project is designed to generate actionable knowledge at both institutional and national levels. The dissemination strategy follows a multi-tiered approach, balancing scientific rigor with healthcare system relevance.

H.1 Internal Reporting to Participating Centers

Each participating institution will receive:

- A confidential institutional report, including:
  - Risk-adjusted outcome rates (e.g., mortality, complication rates)
  - Benchmarking vs. anonymized peer group
  - Data completeness metrics
  - Center-specific improvement potential
- Reports will be:
  - Delivered in digital format
  - Discussed during feedback meetings (virtual or in-person)
  - Accompanied by a brief summary for internal quality governance

H.2 National Aggregate Report

A comprehensive national summary report will be produced and shared with:

- Sponsors (e.g. SPSA, FMCH, H+, BAG)
- Professional societies (SSAPM, surgical and intensive care associations)
- Policy partners (e.g. Swiss Quality Commission)

Contents:

- National outcome rates
- Stratified results (e.g., by risk, age, procedure type, gender)
- Institutional variability (aggregated)

H.3 Scientific Publication and Conference Presentation

- Results will be submitted to peer-reviewed journals in anaesthesia, perioperative medicine, or health services research
- Topics will include:
  - Outcome variability
  - Anaesthesia-related risk factors
  - Gender-specific analysis
  - Predictive modelling
- Authors will be selected in line with ICMJE criteria; all participating centers will be acknowledged

SOCAS findings will also be presented at:

- SSAPM Annual Congress
- European Society of Anaesthesiology (ESAIC)

- Swiss Public Health or Quality Congress
- Potentially international forums (e.g. ISQua, IARS)

H.4 Stakeholder Briefings and Workshops

Results will be prepared in short formats (policy briefs, executive summaries) tailored to:

- Hospital executives and quality boards
- Insurers and health policy stakeholders
- Public health partners (BAG, Obsan)

Optional: A national SOCAS dissemination workshop may be held in Q4 2027 for results discussion and forward planning.

H.5 Data Sharing and Future Use

- Pseudonymized data may be made available to academic collaborators upon request and with SOCAS steering committee approval
- The dataset may support:
    - Secondary research projects
    - Methodological development (e.g. predictive modelling)
    - Integration into national registries (future alignment)

A data access and reuse policy will be developed in line with SPSA and ethics committee guidance.

Appendix I. Project Risk Assessment and Mitigation Plan

SOCAS is designed as a low-risk, non-interventional quality project. Nonetheless, operational and organizational risks must be recognized and managed. This appendix outlines potential risks across key domains and proposes corresponding mitigation strategies.

I.1 Risk Matrix

Risk Area	Specific Risk	Likelihood	Impact	Mitigation Strategy
Ethical approval	Delays in KEK Zurich or multicantonal approval	Medium	Medium	Early KEK submission; use of BASEC templates; ethics consultant review
Site readiness	Variation in onboarding speed; some sites delay start	High	Medium	Rolling site activation; early planning calls; minimum volume thresholds
Data completeness	Missing outcome fields (e.g. 180d mortality)	Medium	High	Clear data definitions; regular monitoring; coordinator training
Follow-up failure	Loss to follow-up for long-stay or external transfers	Medium	Medium	Integration with discharge systems; pragmatic endpoint definitions
Personnel turnover	Site coordinators unavailable or reassigned	Medium	Medium	Backup contact per site; monthly check-ins from central team
IT/system errors	Data entry or transmission issues (A-QUA sync)	Low	High	Real-time data integrity checks; IT support agreement with A-QUA team
Low recruitment	Center provides fewer cases than expected	Medium	High	Over-recruitment plan (12–14 sites); adjust timelines if needed
Public misinterpretation	Benchmarking seen as punitive	Low	Medium	Confidential center reports; aggregated publication policy
Funding gaps	Partial funding; sponsor withdrawal	Medium	High	Tiered funding model; early commitments; supplemental applications

I.2 Monitoring and Governance

- The SOCAS Steering Committee will review risk status quarterly
- Each participating center will designate a site liaison for operational and data oversight
- Any serious deviation (e.g., ethics non-compliance, data breaches) will trigger an immediate internal review

I.3 Escalation and Contingency Planning

- If major milestones are at risk, the study team may:
    - Replace or substitute participating centers
    - Extend the data collection period (within approved timeline)
    - Submit ethics amendments (e.g., cohort changes, technical clarifications)

A final risk and compliance summary will be included in the study's internal close-out report.

Appendix J. Glossary and Abbreviations

J.1 Glossary of Terms

Term	Definition
Anaesthesia-QUAlity (A-QUA)	Swiss national anaesthesia quality documentation system capturing pre-, intra-, and postoperative data for benchmarking and quality improvement.
Anaesthesia CERTification (A-CERT)	Structured, peer-reviewed audit program for assessing structural and process quality in Swiss anaesthesia departments.
ClassIntra Scale	A validated tool for grading intraoperative adverse events according to severity (Classes 0–V).
Clavien-Dindo Classification	A standardized scale for grading postoperative complications based on the therapy required, from Grade I (minor) to V (death).
General Informed Consent	Institutional consent model allowing the use of pseudonymized patient data for quality improvement and research under Swiss law.
Multicantonal Ethics Submission	Ethics approval procedure under BASEC, enabling approval of one protocol for use across multiple Swiss cantons.
Pseudonymization	Replacement of personal identifiers with coded values such that re-identification is not possible without a secure key held locally.
Empirical Bayes Estimator	Statistical method for stabilizing institution-level estimates (e.g., mortality rates) based on center volume and national average.
180-Day Mortality	All-cause death occurring within 180 calendar days of the indexed anaesthesia procedure, assessed via medical records.

J.2 List of Abbreviations

Abbreviation	Full Term
ASA	American Society of Anesthesiologists (risk classification)
A-QUA	Anaesthesia-QUAlity (Swiss quality registry)
A-CERT	Anaesthesia CERTification
BAG	Bundesamt für Gesundheit (Federal Office of Public Health, Switzerland)
BASEC	Business Administration System for Ethics Committees (Swiss online ethics portal)
CAM	Confusion Assessment Method (delirium screening tool)
CI	Confidence Interval
CHF	Swiss Franc
FMCH	Foederatio Medicorum Chirurgicorum Helveticorum
H+	H+ Die Spitäler der Schweiz
HFV	Verordnung über klinische Versuche mit Menschen (Human Research Ordinance)
HFG	Humanforschungsgesetz (Swiss Human Research Act)
ICMJE	International Committee of Medical Journal Editors
ICU	Intensive Care Unit
IQR	Interquartile Range
KEK	Kantonale Ethikkommission
LOS	Length of Stay
PACU	Post-Anaesthesia Care Unit
PI	Principal Investigator
SD	Standard Deviation
SOCAS	Swiss Outcome After Anaesthesia and Surgery
SPHN	Swiss Personalized Health Network
SPSA	Stiftung für Patientensicherheit in der Anästhesie
SSAPM	Swiss Society for Anaesthesiology and Perioperative Medicine

Appendix K. Authorship and Acknowledgements Policy

The SOCAS study group is committed to ensuring that all contributions to the project are appropriately recognized in accordance with the principles of scientific transparency and fairness.

This policy follows the ICMJE (International Committee of Medical Journal Editors) guidelines and reflects norms for multicenter observational research.

K.1 Scientific Authorship

Authorship will be offered to individuals who meet all four ICMJE criteria:

1. Substantial contribution to the conception, design, data acquisition, or analysis of the study
2. Participation in drafting or revising the manuscript critically for important intellectual content
3. Approval of the final version of the manuscript to be submitted
4. Agreement to be accountable for all aspects of the work

K.2 Authorship Model

For each scientific publication:

Role	Eligibility and Assignment
First author(s)	Member(s) of the core SOCAS study team responsible for primary analysis and drafting
Last (senior) author	Chief investigators or lead methodologist
Co-authors	Members of the study group or site PIs contributing to design, analysis, or manuscript development
Collaborators (non-author group)	Participating sites not represented individually in authorship will be listed under “SOCAS Study Group” and acknowledged fully

The full author list will be agreed upon prior to manuscript submission, based on documented contributions.

K.3 Institutional Acknowledgements

All participating centers will be acknowledged in every:

- Scientific publication
- National or institutional report
- Conference abstract or poster

Acknowledgements will include:

- Institution name
- Local study lead (PI)
- Coordinators or supporting staff (where applicable)

If institutional representatives meet authorship criteria, they will be included as co-authors.

K.4 Sponsor and Funding Acknowledgements

The following will be transparently acknowledged:

- Financial support from SPSA, FMCH, H+, BAG, foundations, or others
- Technical support from A-QUA, A-CERT, and affiliated infrastructure providers
- Contributions from the SOCAS advisory board

No funder or sponsor will have editorial influence over scientific publications or study reports.

K.5 Conference Presentations and Abstracts

Abstracts and presentations will:

- List the SOCAS Study Group as institutional authorship where appropriate
- Include core contributing authors by name
- Reflect collaborative input from centers involved in the presented data

Prior to submission of abstracts or talks, content will be reviewed by the SOCAS steering committee for consistency and quality assurance.

Appendix L. Contact Directory

L.1 Chief Investigators

Name	Institution	Role	Email
Prof. Dr. Christoph K. Hofer	Schulthess Klinik Zürich	Chief Investigator	christoph.hofer@kws.ch
Prof. Dr. Michael T. Ganter	Klinik Hirslanden Zürich	Chief Investigator	michael.ganter@hirslanden.ch

L.2 Study Sponsor

Organization	Contact Person	Function	Email
Stiftung für Patientensicherheit in der Anästhesie (SPSA)	tbd (Secretariat/Board)	Legal sponsor and governance	info@spsa-fspa.ch

L.3 SOCAS Study Group – Core Team

Name	Affiliation	Role
Prof. Dr. Thierry Girard	Universitätsspital Basel	Steering Committee
Prof. Dr. Urs Eichenberger	Universitätsklinik Balgrist Zürich	Steering Committee
PD Dr. Caveh Madjpur	Kantonsspital Winterthur	Steering Committee
Dr. Asimina Lazaridou	Schulthess Klinik	Project Coordination

L.4 Advisory Board

Name	Affiliation	Role
Prof. Dr. Rupert M. Pearse	Queen Mary University of London	Scientific Advisor
Prof. Dr. Beatrice Beck Schimmer	Universität Zürich	Institutional Advisor
Andrea Rytz	Schulthess Klinik, Zürich	Strategic/Executive Advisor

L.5 Ethics and Regulatory Contact

Function	Contact	Role
Lead Ethics Submission (KEK Zurich)	Prof. Dr. Christoph Hofer	Submission Coordinator
BASEC Coordination	SOCAS Project Office	Documentation & tracking

L.6 Data Management and Statistics

Role	Contact	Email
Data Management Lead	tbd (A-QUA central coordination)	tbd@spsa-fspa.ch
Biostatistics Lead	tbd (suggested: University partner)	tbd@institution.ch

L.7 Site Coordination (Example Entry)

Each center will complete a standard contact form during onboarding.

Site	Local PI	Study Coordinator	Email
Schulthess Klinik Zürich	Prof. Dr. Christoph Hofer	tbd	christoph.hofer@kws.ch
Klinik Hirslanden Zürich	Prof. Dr. Michael Ganter	tbd	michael.ganter@hirslanden.ch
Kantonsspital Winterthur	PD Dr. Caveh Madjpur	tbd	caveh.madjpur@ksw.ch