SUSTAIN-EUROPE

SUSTAIN-EUROPE Frequently Asked Questions (FAQ)

1. **When should the data be collected?**
   Data should be collected once per case, at any single time point between **5 to 60 minutes after skin incision or the start of the procedure, as applicable**.

2. **How will this data be collected? Will they be obtained directly from the anaesthesia machine/ventilator as raw data, or calculated using variables such as MAC, fresh gas flow, and duration of anaesthesia?**

   The availability and format of source data are expected to vary across participating hospitals in Europe, depending on local documentation systems and anaesthesia workstations. For this multicentre prospective observational study, data collection will primarily be performed using a dedicated mobile application operated by trained study staff. Certain variables, such as fresh gas flow (FGF), may be displayed on anaesthesia workstations without being routinely documented in anaesthesia records. In such cases, values entered directly into the application by the observing staff will constitute the source data, with the application's encrypted audit trail serving as the primary source documentation.

   In exceptional circumstances where use of the mobile application is not possible, centres may record data on paper CRFs and subsequently transfer the information to the eCRF. Copies of all original source documents, whether electronic or paper-based, must be retained securely in accordance with local regulations and accessible only to authorised personnel.

3. **To what extent does SUSTAIN-EUROPE require patient consent for the use of study data?**

   Patient consent requirements are determined by the local Ethics Committee (EC) or Institutional Review Board (IRB), as well as applicable national regulations. The study accommodates both a consent-based approach and a legitimate interest/no-consent approach, depending on local requirements and approvals.

4. **What data is required for the project?**

   Only data that is routinely available as part of anaesthetic care will be collected. The questions shown in the app depend on the type of anaesthesia selected. For example, questions on volatile anaesthetics will only appear if inhalational anaesthesia is used. Participants will therefore not be asked to complete every item

included in the full CRF. Please refer to **Appendix 03 – Case Report Form (CRF)** for detailed information regarding the data to be collected.

5. **Will participating hospitals be able to choose their own week of data collection? What is the expected timeline?**

   Yes. Each participating hospital may select a **predefined working week** for data collection that fits its local schedule. The week can therefore be planned around local circumstances such as holidays, vacation periods, congresses, or other organisational constraints.
   Data collection may begin once all required local approvals and study preparations are in place. A single defined working week should then be selected in advance for data collection at the participating centre.

6. **Should all eligible patients from all active operating rooms during the consecutive five-day study period be included?**

   This is the intended objective of the study. However, it is recognised that including every eligible patient may not be feasible for all participating centres. Centres should make every reasonable effort to achieve comprehensive inclusion.

7. **Is there a minimum number of patients that a centre must recruit?**

   There is no predefined minimum recruitment target. However, the level of contribution and eligibility for investigator recognition will depend on the number of patients enrolled and the extent of active involvement in the study. The Steering Committee (SC) may review cases where recruitment numbers are particularly low and evaluate the legitimacy of collaboration based on other contributions to the project.

8. **What are the requirements for investigator recognition and authorship?**

   The local Principal Investigator (PI) is responsible for identifying staff members who have actively contributed to the study and should be considered investigators. Participating centres will submit these names through the End of Study Reporting Form. The number of investigators recognised per centre is linked to the number of patients enrolled and successfully followed through study completion.

Table 2: Number of investigators named according to number of patients enrolled and followed to completion within the recruitment period:

Number of patients completed	Number of investigators at that centre
>25	1
>50	2
>100	3
>150	4
>200	5
>250	6
>300	7
>450	8
…	…

9. What are the conditions for authorship or collaborator status?

Members of the Steering Committee and National Coordinators may be considered for co-authorship based on their overall contributions to the study. To qualify for authorship, individuals must fulfil all International Committee of Medical Journal Editors (ICMJE) authorship criteria and contribute substantially to centre recruitment and study activities. Final decisions regarding authorship eligibility will be made by the Steering Committee in consultation with ESAIC the main data collected

- **Patient and Procedure Characteristics** (e.g. age, sex, BMI, date and type of procedure, emergency status, etc.)
- **Anaesthesia Practice Variables** (e.g. type of anaesthesia, use of inhalational agents, fresh gas flow settings, medications, monitoring practices, etc.)
- **Ventilation and Respiratory Management**
- **Sustainability-Related Measures** relevant to anaesthesia practice

10. What are the minimum requirements for a participating centre?

A participating centre must:

- Be a department of anaesthesiology within a European hospital or medical centre.

- Register through the Call for Centres process.
- Ensure adequate staffing during the recruitment period.
- Appoint a local Principal Investigator (PI) who is an anaesthetist.
- Obtain all required local regulatory and ethical approvals before study start.
- Complete the pre-study questionnaire, conduct staff training, supervise data collection, and ensure accurate eCRF completion.
- Be able to collect data during a selected 5-consecutive-working-day study period.

11. Is a local Principal Investigator required, and are other anaesthesiologists or trainees able to be registered as local investigators or collaborators?

Each participating centre must have a **local PI who is an anesthetist and leads the study locally**. We need two main contacts per centre: One Principal Investigator (PI) and one secondary contact person.

- Regarding Data Entry: you will be granted 3 accounts to ESAIC **RedCap** where electronic data will be collected - Principal Investigator & Secondary Contact person + a third data entry person
- Regarding Recruitment: as many doctors within your hospital can take part to help ensure recruitment is carried out effectively. However, we still recommend that the Local Principal Investigator keeps a close eye on the process to ensure smooth coordination.

12. What local regulatory or ethics approvals are expected before data collection can begin?

Before starting recruitment and data collection, the local PI must:

- Submit the study documents to the responsible IRB, Ethics Committee, Competent Authority, or equivalent body.
- Obtain written evidence of one of the following:
  - Approval/favourable opinion, or
  - Exemption from the requirement for individual informed consent, where applicable.
- Complete and sign the study approval documentation coversheet and send it to ESAIC.

13. Is any specific training required before recruitment starts?

The protocol requires:

- Local Pis should familiarize themselves with the study protocol.
- Local PIs to train relevant staff involved in study activities.

- Staff obtaining consent or collecting study data to be familiar with the protocol and procedures appropriate to their role.

The protocol does not mandate formal GCP certification for all collaborators, but study conduct follows ICH-GCP principles and training is required before participation.

14. How will data be collected?

Data are collected locally, pseudonymised, and entered into a secure electronic case report form (eCRF) using a secure online database protected by personal usernames and passwords.

The study plans to use a **dedicated mobile application** for data collection by trained staff. The app is intended to serve as source documentation for parameters that may not routinely appear in anaesthesia records. Continuous audit trails are maintained within both the app and the eCRF.

Once we have final data collection form (CRF) and final protocol the documents will be shared with the registered centres. Once the centre complets the mandatory steps (which will be instructed at later stage) the access to the eCRF will be given.

15. The protocol does not define a mandatory minimum recruitment target per centre. Centres are encouraged to:

- Screen all consecutive eligible patients during their chosen study week.
- Aim to recruit all eligible patients where feasible.