ROMANIAN SOCIETY OF ANESTHESIOLOGY AND INTENSIVE CARE
Medical Education and Research Department
no. 156 Liviu Rebreanu street, 300723 Timisoara, Romania
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Study Chief Investigator (CI)

Registered Physician who has overall responsibility for the Trial and has the appropriate education (e.g. PhD student or PhD) and who takes responsibility for: - Submission of a project to SRATI. This submission is usually made on behalf of the Steering Committee. - Submission of the protocol for ethical approval and other necessary regulatory bodies for approvals. - Identification of centres willing to participate in the study. - Advancement of the project to successful conclusion including publication in a peer reviewed journal or journals. - Acknowledging SRATI in all publications and presentations arising from the work.

SRATI Clinical Study Coordinator

The project manager who handles most of the administrative responsibilities of a clinical study and ensures that quality control is applied to all stages of the study. The Clinical Study Coordinator is located at the SRATI Secretariat Office established in Romania and facilitates all aspects of trial administration, working in close collaboration with the Study Committee to finalise the study documents and with the national co-ordinators and study centres to disseminate information.

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Data Safety Monitoring Board

The Data and Safety Monitoring Board is an independent group of experts that advises the Study Committee and the study investigators. The members of the board serve in an individual capacity and provide their expertise and recommendations. The primary responsibilities of the board are to 1) periodically review and evaluate the accumulated study data for participant safety, study conduct and progress, and, when appropriate, efficacy, and 2) make recommendations to the Study Committee concerning the continuation, modification, or termination of the trial. The board considers study-specific data as well as relevant background knowledge about the disease, test agent, or patient population under study.

Local Principal Investigator

The clinician / PhDs / PhD / Clinical Researcher who has overall responsibility for the trial at their centre e.g. patient consent, randomisation, data collection, data return, etc. The Principal Investigator can delegate study related procedures to appropriately trained members of the study team at their centre.

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SRATI CTN for Patient Care

Organisation committed to enhance patient care through research and education, and will help to raise the long-term objectives of the Society. All members of the SRATI CTN agree to abide by the principles and obligations set out below. All contributors to and participants in the SRATI CTN will agree to abide by the principles of ethical conduct in research and good clinical practice (ref. 1* ICH, 6* ISO14155). They will act in the best interests of their patients and of the scientific community.

SRATI CTN Studies Data Property

- The CTN is part of the SRATI.
- For each Study, the study protocol will detail the Sponsorship and the data ownership policy.
- For SRATI sponsored studies, the intellectual property of the data remains under the responsibility of the SRATI.
- In case of collaborative studies with other societies (ESICM, etc.), the ownership of data should be decided upfront in the protocol.

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- The Chief Investigator of the chosen trial is responsible for approval, monitoring, and financial issues of the research project. He/she reports to the chair of the SRATI.
- If needed, an independent evaluation of feasibility of a large-scale project (and evaluation of adequacy of use of financial resources) will be requested from external reviewers' experts in epidemiology or clinical trials.

SRATI CTN Authorship Rules

Chief Investigator and the SRATI CTN agree on authorship order and/or criteria governing authorship in advance. This must be described in the study protocol which is approved by the SRATIC. For each study all efforts should be made with the Journal editor to include the name of the network in the list of authors.