A. Introduction
LUNG-SAFE study (originally endorsed by the ESICM trial group) aimed at assessing the burden of, management and therapeutic approaches to, and outcomes from acute hypoxaemic respiratory failure requiring ventilatory support, with a specific focus on ARDS.

The study was performed in 2014, screening almost 30,000 patients, enrolling 12,911 out of which 4,530 had acute hypoxaemic respiratory failure and more than 3000 had ARDS.

All the data were collected on a voluntary basis by the investigators, under the agreement that all the Lung-Safe investigators would have had the possibility to propose additional studies requiring data analyses not covered by the original manuscript.

To this end, the ESICM Trial Group endorsed the “OPEN-LUNG-SAFE” initiative, whose policies for data access, publication and authorship are described below.

The objectives of this policy are:
- To allow each LUNG-SAFE investigator to propose secondary analysis of the database, avoiding overlaps and duplicate studies.
- To assure timely dissemination of LUNG SAFE Investigators findings to the scientific community.
- To maintain high scientific standards for published material.
- To assure equitable investigator participation and attribution of authorship in presentations and publications.
- To prevent publications that:
  a. are factually or conceptually inaccurate
  b. prematurely release data which might subsequently preclude publication of results in high quality peer reviewed journals
  c. are redundant
C. Executive committee for OPEN-LUNG-SAFE initiative
To facilitate the review process of applications and to optimize the coordination of different studies the Steering committee of LUNG-SAFE will appoint an executive committee (and its chairman) for the OPEN-LUNG-SAFE (OLS-EC) initiative

B. Proposals for Secondary Publications arising from LUNG-SAFE Study
B1. The Steering committee encourages LUNG-SAFE investigators to submit suggestions for additional analyses that would result in secondary publications and presentations.
B2. A formal invitation to submit proposals will be issued in two steps. Members of the LUNG-SAFE steering committee will have a period of two weeks to submit their proposals. Afterwards all the LUNG SAFE investigators will have the possibility to submit proposals. Calls will be issued periodically (about four times a year). Each call will have a deadline.
B3. A proposal form is available on the ESICM website, and should be used for all such proposals, otherwise submissions will not be evaluated.
B4. These proposals will be forwarded to the OLS-EC for approval. Proposals from LUNG-SAFE investigators (i.e. site investigators and national coordinators) will take priority. We anticipate that all requests for scientifically sound sub-analyses will be approved by the OLS-EC.
B5. Investigators who received any financial support (academic or industrial), specifically directed to the investigation proposed, should disclose this in the request form.
B6. Evaluation of the proposals will consist in a two-steps process.
B7. The first step is aimed at evaluating the general soundness of the proposal and the potential conflict/overlap with other proposals. In the case that data is insufficient to answer a particular question investigators might be asked to refine their hypothesis accordingly. For duplicate or overlapping requests, the OLS-EC will attempt to facilitate the collaboration between the proponents; if this cannot be achieved, the first investigator who submits the request will have priority.
B8. If the proposal is approved at the first stage, proponents will be requested to submit a detailed statistical analysis plan, which also will undergo evaluation from the OLS-EC.
B9. After OLS-EC approval, final proposals will be circulated to the LUNG-SAFE steering committee with a tacit approval rule.
B10. Investigators should normally expect a response on their proposal within four weeks.
B11. The titles of approved (and hence undergoing) proposals will be posted on the LUNG-SAFE page of the ESICM website, to facilitate further applicants in avoiding overlaps.

C. Manuscript preparation
For the purposes of maintaining data integrity, none of the “raw” data can be disclosed directly to the investigators.
The statistical analysis will be performed by statisticians appointed by the OLS-EC, according to the approved SAP.
The OLS-EC must review all manuscripts prior to submission for publication. This added layer of peer review should increase the quality of the sub-analyses and will serve as a final check on duplicate reports.
For all manuscripts describing secondary analyses, the finalization of the (a) study hypothesis; (b) study design; (c) statistical analysis plan; and (d) data interpretation; as well as the overall handling of the manuscript will be managed by the OLS-EC committee PLUS the investigators that submitted the relevant proposal that was approved by the OLS-EC.
Investigators are not allowed to disclose data to third parties before manuscript publication

D. Rules of authorship
Attribution of authorship is expected to vary by type of publication or presentations. Procedures for each are detailed below.

Examples of investigator initiated publications or presentations include those generated by probing the LUNG SAFE database, or the publication of one of the predefined sub-studies [e.g. READS, ASTEROID, etc]; and those which utilize LUNG SAFE resources but are not study primary endpoints.

The Writing Committee and its chairman will be appointed by the OLS-EC, taking into account the suggestions of the investigator(s) proposing the study; the presence of one or two members of the original LUNG-SAFE steering committee is highly recommended. Modifications to the initially approved writing committee will not be possible unless in the case of clear and cogent motivations.

The first named author will usually be the person that led the sub-study and/or proposed the additional analysis of the LUNG SAFE database.

In all cases where LUNG SAFE data or other resources are utilized, the “LUNG SAFE Investigators and the ESICM Trials Group” will be credited as an author in the manuscript and the entire list of investigators will be included as collaborators.

E. Submission Policy

Submission to the ESICM journal “Intensive Care Medicine” is strongly encouraged.

In the case of submission/publication fees, these will have to be covered by the PI of the proposals or by one of the members of the writing committee.

F. Abstracts

Abstracts generated by the Writing Committees appointed as above described should reflect the topic of the original proposals (and hence of the manuscript being drafted). All abstracts will be reviewed by the OLS-EC within 2 weeks of receipt. The approved, edited, abstract will be circulated to all co-authors for comment prior to submission. Co-authors comments are expected to be sent to the Writing Committee chairman within two weeks. Because of limited space in abstracts, the chairman of the writing committee (or his/her designee) will be the first author, followed by "The LUNG SAFE Investigators". The same person will also act as presenter during the conference.

In the case of submission fees, these will have to be covered by the PI of the proposals or by one of the members of the writing committee as well as the expenses for the conference abstract presentation.