



ERS EUROPEAN
RESPIRATORY
SOCIETY
every breath counts

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ERS Guidelines for Pragmatic Trials Endorsement

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1 Objectives

- To recognise key pragmatic clinical trials in the respiratory field, organised by external organisations.
- To enable countries to join pragmatic studies led in other countries in Europe
- To facilitate and potentially allow leveraging of national funding under the umbrella of a cross-european research trial.

2 Endorsement criteria

The proposed trial should fulfil the following criteria:

- Interventional randomized controlled trials
- Open label
- International trial
- Real-world settings
- Independent, investigator-initiated
- Led by a European Country
- Regulatory and Approved by the competent authorities
- Registered in trial registry (e.g. www.clinicaltrials.gov)
- International: major interest by several other countries / National Respiratory Societies
- In one of the 8 major respiratory disease domains
- In concertation with the respective ERS Assembly (and ERS CRC)
- Adequate methodology and primary endpoint (effectiveness)
- Adequate quality assurance and pharmacovigilance processes
- Funding in place

Important:

The ERS is unable to endorse pragmatic trials where financial support is received from a **single sponsor, when organised by industry or for-profit entity.**

3 Procedure

- The coordinating investigator must return the completed application form to the ERS office (scientific@ersnet.org): at least 4 months' advanced notice is advised.
- This application will be forwarded to the relevant groups of reviewers who will:
 - review the application with particular regard to the objectives and the scientific relevance of the study;
 - assess the interest of the ERS in endorsing the study;
 - provide inputs to the final decision's makers
- The ERS decision (including major comments) will be sent to the coordinating investigator by the ERS Office.

4 Endorsement benefits and collaboration

Upon approval, the ERS will:

- advertise the project on the [ERS website](#)
- promote the project through communication channels (such as Twitter or Facebook when applicable).
 - Please note that no direct mailing can be sent for an endorsed project.
- share news from your project as news articles on the ERS website where applicable. Please send on any press releases to the ERS communications team: dawn.ould@europeanlung.org

Note that:

- The ERS endorsement does **NOT** involve financial or administrative support by the ERS.

In exchange the Coordinating Investigators of the event should:

- Mention "**Endorsed by the ERS**" with the ERS name and logo printed on printed or electronic document. Any use of the ERS logo needs to be approved by the ERS Office in advance;
- Submit the annual reports due to Ethics Committees to the ERS Office.