# Application for ERS Pragmatic Trial Endorsement

# *To be submitted (including all appendixes):*

##### ERS Headquarters at [scientific@ersnet.org](mailto:scientific@ersnet.org)

*The ERS will endorse the Pragmatic Trial and promote it accordingly to its members. Kindly refer to the ERS Guidelines for PragmaticTrials Endorsement available on the same web-section of this form.*

**General information**

**Title of the clinical trial**

Link for online information / website:

**Main respiratory diseases: *(please select one)***

Airway diseases

Interstitial lung diseases

Paediatric respiratory diseases

Pulmonary vascular diseases

Respiratory critical care

Respiratory infections

Sleep and breathing disorders

Thoracic oncology

**Coordinating Investigator/Principal Investigator**:

Name

Address

E-mail

Phone

ERS Member  Yes.  No.

**Legal sponsor:**

Name

Address

Is it registered in a clinical trial registry (e.g. [www.clinicaltrials.gov](http://www.clinicaltrials.gov))?  Yes.  No.

If yes, please provide registration ID

### Trial summary

**Patient population: age (range), disease (severity; stage; phenotype), ...**

**Intervention: treatment (e.g. drug A)**

**Control: treatment (e. g. drug B)**

**Outcome: primary outcome; key secondary outcomes**

**Treatment duration**

**Trial timelines**

First patient, first visit:

Last patient, first visit:

Last patient, last visit:

Data maturity for primary endpoint

*Please include a figure showing the different trials phase!*

**Operational information**

**List of participating countries/sites**

**Please provide information on the funding secured to conduct the pragmatic trials!**

**Please provide information on the processes and resources in place to ensure quality!**

*E.g. SOPs, on-site and central monitoring, data management, auditing…*

### Documents to be submitted as appendices

### Yes No

### CV and GCP certificate of the Coordinating Investigator/Principal Investigator

### Clinical trial protocol

Regulatory approval for the leading country

Report of peer-reviewing processes by major funders (if any)

**Conflict of interest**

The Coordinating Investigator/Principal Investigator must provide duly completed and signed conflict of interest forms with the Meeting Endorsement application.

Date of submission:

Name of the meeting Organiser/s:       Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Tobacco-Industry related conflict of interest**

*(Organisers)*

*Please complete and tick R the following statements as appropriate.*

ERS does not accept collaboration with individuals who are receiving funding from the tobacco industry.

In the case of **disclosure** of a conflict of interest any time after **1/1/2000** by the person concerned, there is a **5-year ban** from the date of disclosure before that person is allowed to participate actively in an ERS activity.

Where a **conflict of interest is discovered and not disclosed**, there is a **ban for life** from participating or collaborating in any ERS activity. The same ban applies to any undisclosed other real or perceived, direct or indirect links with the tobacco industry, such as the holding of shares, speaking at or attending meetings organised by the tobacco industry.

Where any person is found to be **maintaining a relationship** with, or **receiving funding from**, the tobacco industry after **1/1/2013** there will be a ban for life from involvement in any ERS activity and collaboration.

Please select what applies to you:

I declare that I have had **NO** relationship of any kind with the tobacco industry (since 1/1/2000), nor will have a link to the tobacco industry before the event to which I have been invited by the ERS to participate in.

**Yes**, I declare that I have or have had a relationship with the tobacco industry after 1/1/2000 and before 1/1/2013. *NOTE: ERS will have to cancel this collaboration and you will be banned from all ERS activity for 5 years.*

**Yes**, I declare that I have or will have a relationship with the tobacco industry after 1/1/2013. *NOTE: The ERS no longer accepts Faculty who has links with the tobacco industry, the ERS will have to cancel this collaboration and you will be banned for life from all ERS activity.*

Name of the meeting Organiser/s:       Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

### Final documents

It is furthermore agreed that if the ERS agrees to endorse the Pragmatic trial, the ERS logo and name will be indicated on the official documents of the Pragmatic trial. The documents where the ERS logo and name will be used, have to be shared prior to publication to the ERS Office (mail: [scientific@ersnet.org](file:///\\filesrv3\DocEntrep\Scientific%20Committee\endorsement%20meetings\Forms%20&%20rules%202018\scientific@ersnet.org))