

# INTRODUCTION TO ERN-LUNG

## **Francesco Bonella**

Interstitial and Rare Lung Disease Unit, Ruhrlandklinik, University Hospital,  
Essen, Germany

DPDL group Chair elected

ERN-LUNG ILD Core Network Coordinator




# Disclosures

<b>Relationships that could be relevant for this meeting</b>	<b>Company names</b>
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# Rare respiratory diseases are ready for primetime: from Rare Disease Day to the European Reference Networks

Marc Humbert <sup>1,2,3</sup> and Thomas O. Wagner<sup>4</sup>

**Affiliations:** <sup>1</sup>Faculté de Médecine, Université Paris-Sud, Université Paris-Saclay, Le Kremlin Bicêtre, France. <sup>2</sup>Service de Pneumologie, Centre de Référence de l'Hypertension Pulmonaire, Hôpital Bicêtre (Assistance Publique Hôpitaux de Paris), Le Kremlin-Bicêtre, France. <sup>3</sup>Inserm UMR-S 999, Hôpital Marie Lannelongue, Le Plessis Robinson, France. <sup>4</sup>Frankfurt Reference Center for Rare Diseases (FRZSE), Dept. of Pneumology and Allergology, Universitätsklinikum Frankfurt am Main, Frankfurt am Main, Germany.

**Correspondence:** Marc Humbert, Service de Pneumologie, Centre de Référence de l'Hypertension Pulmonaire, Hôpital Bicêtre (Assistance Publique Hôpitaux de Paris), 78 rue du Général Leclerc, Le Kremlin-Bicêtre, 94270, France. E-mail: marc.humbert@daphp.fr

# European Reference Networks: Background



- The creation of ERNs stems from the **Directive on patients' rights in cross-border healthcare**. The goal of the Directive is to foster **expertise, knowledge transfer and diagnosis & care excellence** across Europe for rare diseases
- The Directive is NOT about identifying new reference centres. According to the legislation, **the main added value of ERNs is to:**
  - **facilitate improvements in access to diagnosis and delivery of high-quality, accessible and cost-effective healthcare** for people living with rare diseases
  - act as focal points for **medical training** and research, information dissemination and evaluation, especially for rare diseases
- Prerequisite for ERNs' formation is the aggregation of **at least 10 different healthcare providers (HP) from 8 EU countries**
- Each network is also defining **specific criteria to reflect expertise in their field**
- In March 2016, the European Commission opened the first call for the creation of ERNs

# List of Approved ERNs

- In December 2016, the European Reference Network Board of Member States approved the first **23 ERNs**
- **370 hospitals and almost 1000 highly specialised units are involved across the 23 ERNs**

1. ERN BOND	European Reference Network on Rare Bone Disorders
2. ERN CRANIO	European Reference Network on Rare craniofacial anomalies and ENT disorders
3. Endo-ERN	European Reference Network on Rare Endocrine Conditions
4. ERN EpiCARE	European Reference Network on Rare and Complex Epilepsies
5. ERKNet	European Rare Kidney Diseases Reference Network
6. ERN RND	European Reference Network on Rare Neurological Diseases
7. ERNICA	European Reference Network on Rare inherited and congenital anomalies
<b>8. ERN LUNG</b>	<b>European Reference Network on Rare Respiratory Diseases</b>
9. ERN Skin	European Reference Network on Rare and Undiagnosed Skin Disorders
10. ERN EURACAN	European Reference Network on Rare Adult Cancers (solid tumours)
11. ERN EuroBloodNet	European Reference Network on Rare Haematological Diseases
12. ERN EURO-NMD	European Reference Network for Rare Neuromuscular Diseases
13. ERN EYE	European Reference Network on Rare Eye Diseases
14. ERN GENTURIS	European Reference Network on Genetic Tumour Risk Syndromes
15. ERN GUARD-HEART	European Reference Network on Uncommon And Rare Diseases of the HEART
16. ERN ITHACA	European Reference Network on Rare Congenital Malformations and Rare Intellectual Disability
17. MetabERN	European Reference Network for Rare Hereditary Metabolic Disorders
18. ERN PaedCan	European Reference Network for Paediatric Cancer (haemato-oncology)
19. ERN RARE-LIVER	European Reference Network on Rare Hepatological Diseases
20. ERN ReCONNET	Rare Connective Tissue and Musculoskeletal Diseases Network
21. ERN RITA	Rare Immunodeficiency, Autoinflammatory and Autoimmune Diseases Network
22. ERN TRANSPLANT-CHILD	European Reference Network on Transplantation in Children
23. VASCERN	European Reference Network on Rare Multisystemic Vascular Diseases

# Role of the European Commission

- **IT Platform**

- The European Commission will develop and give access to a centralised IT Platform. The IT platform will be made up of generic modules that will be adapted for the different thematic fields of the ERN (for example exchange of clinical information and patient data)

- **Coordination with Board of Member States (BoMS)**

- The Commission will help address issues of cross-border care with the Board of Member States and will act as a liaison between the ERNs and the BoMS

- **Funding**

- Funding is provided for Network coordination through CHAFEA (an agency of the European Commission in charge of implementing the Health Programme)
- Potentially, in the future, more calls could be open for ERNs only

# ERN-LUNG General Presentation

- **MISSION:** ERN-LUNG is a Network of European Healthcare Providers dedicated to **ensuring and promoting excellence** in care and research **to the benefit of patients affected by rare respiratory diseases.**
- **VISION:** to be a **European knowledge hub** for rare respiratory diseases and **to decrease morbidity and mortality from rare respiratory diseases** in people of all ages.
- **OBJECTIVES:** the 5-year plan of ERN-LUNG aims at fulfilling the following objectives:
  - **Taking stock of existing expertise** at European level in the area of rare respiratory diseases **to assess gaps and identify solutions**
  - **Improving cross-border collaborations** for improved continuity of care and providing highly specialised patient-centred care in rare respiratory diseases
  - Advancing innovation in medical science by **reinforcing research, epidemiological surveillance** like registries, **clinical trials, and provide training for healthcare professionals**
  - Ensuring **access to quality and accurate information** on rare respiratory diseases
  - **Strengthening the skills**, competencies and abilities of target groups (ERN-LUNG Full and Affiliated Members, ERN-LUNG Supporting Partners, Patient Groups, External audiences)

# ERN on Rare Respiratory Diseases (ERN-LUNG)

- ERN-LUNG is dedicated to **rare respiratory diseases**
- Coordinated by **Prof. Thomas Wagner** (cystic fibrosis specialist) of the University of Frankfurt and **Prof. Marc Humbert** (pulmonary hypertension specialist) of Bicêtre Hospital in Paris (Vice-Coordinator)
- ERN-LUNG is made up of **60 centres from 12 countries** and **organised across 9 functional committees** covering horizontal topics and 9 core networks covering different diseases of the rare respiratory disease field:

## FUNCTIONAL COMMITTEES

RESEARCH & CLINICAL TRIALS	ETHICAL ISSUES	REGISTRIES & BIOBANKS
PATIENT REPORTED OUTCOMES & QUALITY OF LIFE	QUALITY MANAGEMENT	GUIDELINES & BEST PRACTICES OF CARE
COMMUNICATION & OUTREACH	CROSS-BORDER CARE	TRAINING & CONTINUED MEDICAL EDUCATION

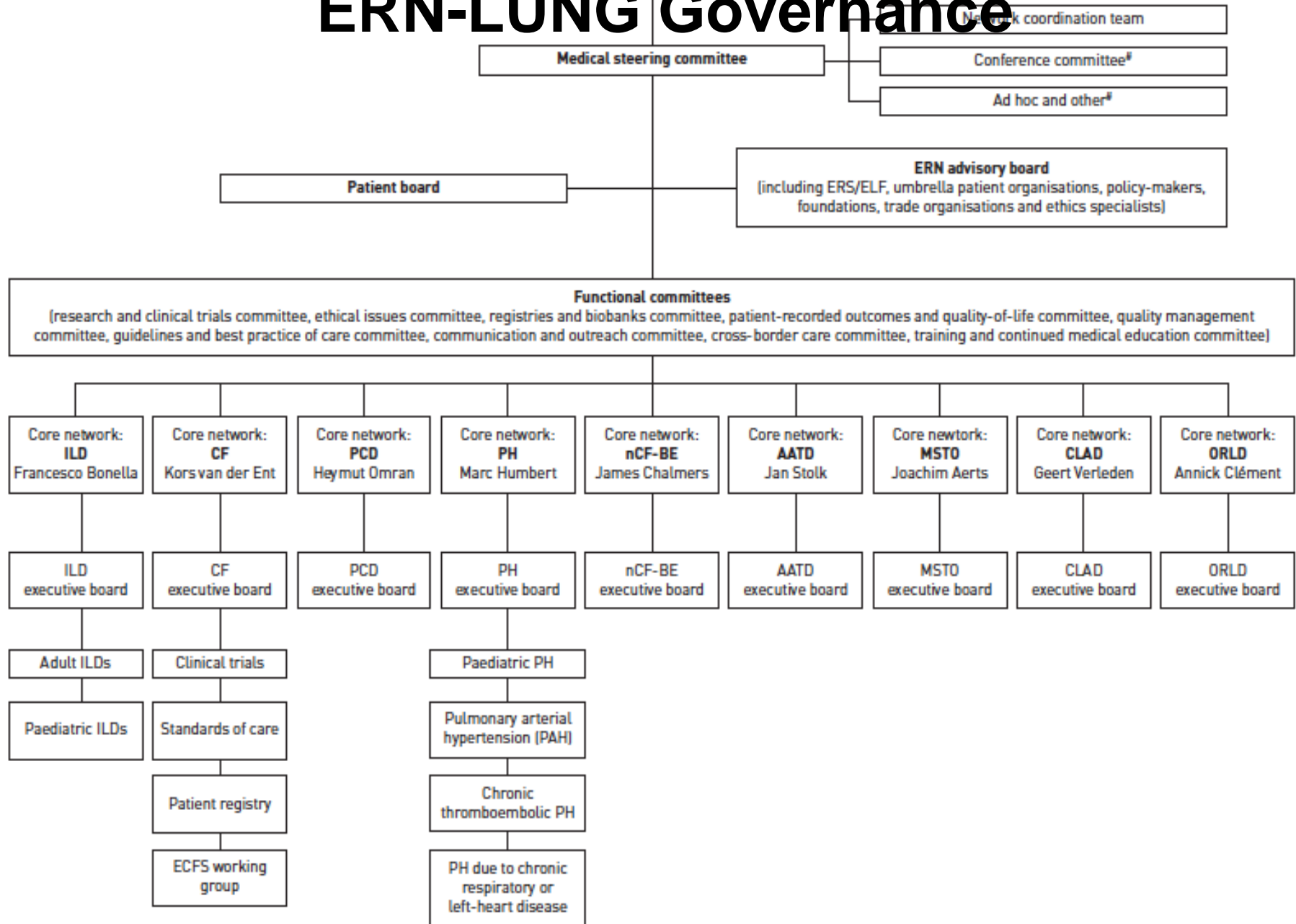
## CORE NETWORKS

INTERSTITIAL LUNG DISEASES	CYSTIC FIBROSIS	PULMONARY HYPERTENSION
PRIMARY CILIARY DYSKINESIA	NON-CF BRONCHIECTASIS	ALPHA 1 ANTITRYPSIN DEFICIENCY
MESOTHELIOMA	CHRONIC LUNG ALLOGRAFT DYSFUNCTION	OTHE RARE LUNG DISEASES



**ERN-LUNG board**  
(representatives from all providers, patient groups and other third-party stakeholders)

# ERN-LUNG Governance



# ERN-LUNG Board

- Sovereign body of the Network
- Composition and voting rules:
  - Includes all Healthcare Providers that are either Full Members or Affiliated Members.
  - Each Full or Affiliated Member has one vote.
  - Decisions are taken by simple majority
- Role:
  - Develops ERN LUNG's Strategic Roadmap and Annual Plans.
  - Elects the Coordinator and Vice Coordinator for a duration of 5 years
  - Empowers the Medical Steering Committee to direct and conduct the general activities and business of ERN-LUNG

# Medical Steering Committee

- Composition and voting rules:
  - Coordinator, Vice Coordinator, past-Coordinator, a representative-elect from each Core Network and Functional Committee and two patient representatives appointed by the Patient Board
  - Mandate is 5 years, except for patient representatives (2.5 years, to ensure a fair rotation)
  - Decisions are taken at the majority of voting members
- Role:
  - direct and conduct the daily activities
  - supervise the activities of both the **Functional Committees** and the **Core Networks**.
- The MSC should aim to meet in-person at least twice a year

# MSC Current Composition

<b>Network coordinator</b>	TOF Wagner, Frankfurt, Germany
<b>Network Vice Coordinator</b>	Marc Humbert, Paris, France
<b>Interstitial lung disease (ILD) Core network coordinator</b>	Francesco Bonella, Essen, Germany
<b>Cystic Fibrosis (CF) Core network coordinator</b>	Kors van der Ent, Utrecht, The Netherlands
<b>Primary Ciliary Dyskinesia (PCD)</b>	Heymut Omran, Muenster, Germany
<b>Pulmonary Hypertension (PH) Core network coordinator</b>	Nazzareno Galiè, Bologna, Italy
<b>non-CF Bronchiectasis (nCF-BE) Core network coordinator</b>	James Chalmers, Dundee, UK
<b>Alpha1 -Antitrypsin deficiency (AATD) Core network coordinator</b>	Jan Stolk, Leiden, The Netherlands
<b>Mesothelioma (MSTO) Core network coordinator</b>	Joachim Aerts, Rotterdam, The Netherlands
<b>Chronic lung allograft dysfunction (CLAD) Core network coordinator</b>	Geert Verleden, Leuven, Belgium
<b>Other rare lung diseases (ORLD) Core network coordinator</b>	Annick Clement, Paris, France
<b>Research and Clinical Trials Committee</b>	Tim Lee, Dundee, UK
<b>Ethical Issues Committee</b>	Carlo Vancheri, Palermo, Italy
<b>Registries and Biobanks Committee</b>	TOF Wagner, Frankfurt, Germany
<b>Patient Recorded Outcomes and Quality of Life Committee</b>	Simon Gibbs, London, UK
<b>Quality Management Committee</b>	Petra Pennekamp, Münster, Germany
<b>Guidelines and Best Practice of Care Committee</b>	Nazzareno Galiè, Bologna, Italy
<b>Communication and Outreach Committee</b>	Christopher Johnson, Cambridge, UK
<b>Cross Border Care Committee</b>	Pavel Drevinek, Prague, Czech Republic
<b>Professional Training and Continued Medical Education Committee</b>	Marlies Wijzenbeek, Rotterdam NL
<b>Patient Board</b>	Hilde De Keyser (CFE, Belgium)
<b>Patient Board</b>	Gergely Meszaros (PHA Europea, Hungary)

# Role of the Core Networks and the Functional Committees

## Core Networks

- responsible for the **development of specific plans for their disease groups**, aligned with the overall ERN-LUNG's strategy
- **provide input and implement the various activities** identified within the work packages lead by the Functional Committees

## Functional Committees

- promote the **interoperability of the Core Networks** in areas that have been recognized
- assist in **developing the deliverables** of the annual plan
- coordinate the **implementation of the work packages**, along topical issues, with input from all Core Networks, and relevant governance bodies

# Patient Board

- Composition:
  - ePAGs
  - Groups proposed by Core Network Coordinators
- Role:
  - To provide a platform for exchange to all patient groups involved in ERN-LUNG
  - To actively contribute to the activities and implementation of ERN-LUNG's annual plans



# Patient Board Current Composition

European patient advocacy group (EPAG)	Hilde De Keyser (Cystic Fibrosis Europe, Belgium)
European patient advocacy group (EPAG)	Luc Matthysen (PHA Europe, Belgium)
European patient advocacy group (EPAG)	Filippo Martone (Amici Contro la Sarcoidosi Italia Onlus, Italy)
European patient advocacy group (EPAG)	Bernd Quadder (Deutsche Sarkoidose-Vereinigung e.V., Germany)
European patient advocacy group (EPAG)	Gergely Meszaros (PHA Europea, Hungary)
European patient advocacy group (EPAG)	Pippa Powell (ELF, UK)
European patient advocacy group (EPAG)	Patrick Vandorpe, Belgium (president of HALO)
European patient advocacy group (EPAG)	P. Ferrari, Italy
European patient advocacy group (EPAG)	Bernhard Rindlisbacher MD, Steffisburg, Switzerland
Interstitial lung disease (ILD)	Liam Galvin, Secretary, EU-IPFF, Thurles, IRE
Cystic Fibrosis (CF)	1 other Cystic Fibrosis Europe (CFE) representative
Primary Ciliary Dyskinesia (PCD)	Bernhard Rindlisbacher MD, Steffisburg, Switzerland
Pulmonary Hypertension (PH)	P. Ferrari, Italy
non-CF Bronchiectasis (nCF-BE)	Marta Almagro, ELF, Bronchiectasis Patient Advisory Group, Portugal
Alpha1 -Antitrypsin deficiency (AATD)	Frank Willersinn, Alpha 1 Global
Mesothelioma (MSTO)	Kate Hill, June Hancock, Mesothelioma Trust, UK
Chronic lung allograft dysfunction (CLAD)	Patrick Vandorpe, Belgium (president of HALO)
Other rare lung diseases (ORLD)	Carlee Gilbert, CHILD EU, UK

# What can ERN-LUNG bring you?

- Funding opportunities
  - Registries call is open to ERNs only
  - The Commission is also working with the Board of Member States to define ways to earmark future research projects specifically for ERNs
- Networking opportunity between reference centres and upscaling of existing good practices/ initiatives
- Potential to publish work of ERN-LUNG in peer-reviewed journals such as the ERJ to highlight the work done within the Network



# What next?

- **March 9/10, 2017, Vilnius** : 3rd ERN Conference with proclamation of the accredited ERNs
- **March 15, 2017**: Signature of the Agreement (mandate) by the ERN Coordinators and the European Commission
- **April 5/6, Frankfurt**: face to face meeting of all Members of ERN-LUNG and official start

# Year 1 activities – general overview

YEAR 1 SPECIFIC OBJECTIVES	YEAR 1 TASKS
<b>WP1 Management:</b> Set up a Network management and coordination system to ensure ERN-LUNG delivers on its long-term objective	Task 1 – Finalise the multi-annual strategic plan of ERN-LUNG and complete administrative processes for registration Task 2 – Establish an internal communication and coordination mechanism Task 3 – Develop Core Network's Action Plans Task 4 - Organization of 1 ERN-Lung Board Meetings Task 5 – Coordination with other ERNs Task 6 – Knowledge management and IP protection
<b>WP2 Dissemination:</b> Create a robust dissemination and communication plan to ensure the activities of ERN-LUNG are amplified and reach their target audiences	Task 1 - Dissemination Plan Task 2 – External communication
<b>WP3 Data gathering:</b> Develop a data gathering and sharing system to enable proper exchange of information, internally and externally	Task 1 -Data-gathering for update of EC IT Platform
<b>WP4 Quality of care:</b> Pave the way to the proper implementation of cross-border care and pathways to improve quality of care for patients across the EU	Task 1 - Guidance Document on multi-disciplinary teams Task 2 - Roadmap of clinical guidelines to be prepared
<b>WP5 Training:</b> Develop a training and education plan to facilitate continuous learning, and cross-sharing of expertise within the Network	Task 1 – Needs assessment Task 2- Educational 5-year Plan
<b>WP6 Research:</b> Identify research gaps to develop a strong research plan and prepare for future research funding applications at EU level	Task 1 -Strategic research plan Task 2 –Annual report on research projects
<b>WP7 Evaluation:</b> Adopt a robust external and internal evaluation policy to measure ERN-LUNG's performance against Network operational objectives	Task 1 – Develop evaluation mechanism Task 2 - Annual Reporting

# Y1 Activities – Overview of H1 deliverables

" No	Deliverable name	Content specification	Delivery month
1.2	<b>Internal communication and reporting forms and calendars</b>	Templates for shared internal communication for all ERN-LUNG bodies Shared calendars including dates for TCs and Meetings and reporting schedule for Core Network coordinators Monthly reports (newsletters from Coordinator)	M1 M1 M1-12
1.5	<b>Coordination with other ERNs</b>	Identify and link with all other ERNs and other projects Quarterly information exchange with overlapping ERNs	M1-12 M4, M8, M12
2.2	<b>Information for HCPs (internal comms)</b>	Development of guidelines for ERN-LUNG's Full Members to communicate about their membership	M2
1.1	<b>Network's strategic plan and administrative set-up</b>	ERN-LUNG 5-year programme Legal registration of ERN-LUNG By-laws and signed statements of members' responsibilities and roles All positions filled	M3 M3 M3
1.3	<b>Core Network's Action Plans</b>	Each of the 9 Core Networks has developed an action plan for the next five years	M3
1.4	<b>1st ERN-LUNG Board Meeting</b>	Preparation of agenda, invitation, organisation of 1st Board meeting	M3
2.1	<b>Dissemination Plan</b>	Development of a full five-year external and internal dissemination plan (newsletters, websites, communications trainings, scientific and lay media targets, social media activity, etc.)	M3
3.1	<b>Data-gathering for update of EC IT Platform</b>	Inventory of Accredited Centres in the area of Rare Pulmonary Diseases in EU 28 MS List of diagnostic technologies and services accredited Inventory of existing registries and biobanks	M3 M4 M5
7.1	<b>Evaluation plan</b>	Tools for monitoring and reporting	M3
7.5	<b>Conflict of interest policy and annual disclosure forms</b>	Development of a conflict of interest policy	M3
7.2	<b>specific performance and outcome indicators for Healthcare Providers</b>	Delphi consultation to select the indicators	M3-9
5.1	<b>Education programme</b>	Needs' assessment of HCPs and of patients (questionnaire)	M3-9
6.1	<b>Research plan</b>	Gaps analysis of current research projects	M5
2.3	<b>External communication</b>	Promotional materials and content for EC IT website (downloadable brochure about ERN-LUNG)	M6
4.1	<b>Guidance Document on multi-disciplinary teams</b>	Review of needs per Core Network, in coordination with functional committee, to develop recommendations for MDT teams for ERN-LUNG through a consensus meeting	M6

# Y1 Activities – Overview of H2 deliverables

" No	Deliverable name	Content specification	Delivery month
3.1	Data-gathering for update of EC IT Platform	Guidance document for eHealth services	M12
7.5	Conflict of interest policy and annual disclosure forms	Annual publication of HCP declarations	M12
7.2	specific performance and outcome indicators for Healthcare Providers	Delphi consultation to select the indicators Agreement on indicators	M3-9 M10
5.1	Education programme	Needs' assessment of HCPs and of patients (questionnaire) Analysis of needs' assessment to develop 5-year educational and training programme	M3-9 M10
6.1	Research plan	Development of 5-year research plan for ERN-LUNG, including EU funding opportunities to target	M9
1.6	Knowledge management and IP protection plan	Knowledge management and IP protection plan is developed, reviewed and adopted in year 1	M6-9
7.3	Common tool for measurement of patient experience	Internal consultation with HCPs and patients Agreement on the content of the tool for roll-out in year 2	M6-9 M10-12
2.4	Online expert advice system	Development and Coordination of the online expert advice system	M8-12
2.5	ERS workshop	Organisation of a workshop at the annual ERS Congress	M9
4.2	Roadmap of clinical guidelines to be prepared	Gap analysis of existing guidelines for diseases covered by ERN-LUNG, coordination with overlapping ERNs to develop a 5-year roadmap of guidelines to be created or updated	M9
7.4	Patient safety data and reporting policy	Development of a unified framework to monitor and improve safety standards	M10
6.2	Annual report on research projects and clinical trials	Development of a report on research activities	M12
7.6	Annual reporting	Annual Network Reporting	M12

# Thank you for your attention!



**European  
Reference  
Network**

for rare or low prevalence  
complex diseases



**RARE DISEASE DAY®**

[http://ec.europa.eu/health/rare\\_diseases/european\\_reference\\_networks/erf\\_en](http://ec.europa.eu/health/rare_diseases/european_reference_networks/erf_en)