



Success and continuous growth of the ERS clinical research collaborations

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This editorial describes the ERS CRC programme, which addresses research areas across all major respiratory disease domains. It explains how the ERS Research Agency supports the CRCs to obtain external funding and ensures links with other ERS activities. <https://bit.ly/2WHIQPa>

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In 2013, the European Respiratory Society (ERS) established the Clinical Research Collaborations (CRC) programme [1] with the aim to support research in different areas of respiratory medicine through European-wide multicentre networks of researchers, from both within and outside of the Society. CRCs are built on multidisciplinary pan-European networks of researchers in specific disease areas, with the aim of building research infrastructures (cohorts, databases, *etc.*), identifying outstanding research questions, developing innovative research protocols, conducting large-scale clinical studies and facilitating the search for external funding. The CRC programme [2] is overseen by the CRC Director who, supported by the CRC working group, regularly reports to the ERS Science Council.

Since 2013, the programme has been very successful, as measured by increased external funding and diversification of projects, and has expanded accordingly. There are currently 23 ongoing CRCs spread over eight major respiratory disease domains: airways disease, interstitial lung diseases, pulmonary vascular diseases, sleep and breathing disorders, respiratory critical care, paediatric respiratory disease, respiratory infections and thoracic oncology (figure 1). Along with the ERS, the European Lung Foundation (ELF) plays a central role to support patient participation in the selection and conduct of projects to ensure that the overall ERS priorities match their expectations.

The CRC provides the opportunity to connect with other ERS activities, like research seminars, development of official ERS scientific documents (guidelines, statements and technical standards), and pragmatic trial endorsement. This is important, since a CRC is an excellent platform to facilitate a successful research seminar and applications for task forces. Research seminars are a tool to not only foster scientific exchange within the CRC consortium, but to also foster interaction with the broader ERS membership, to increase the number of participating network partners and to expand the visibility of the CRC. In addition, a research fellowship [3] embedded in a CRC represents an excellent opportunity for young researchers to expand their research network which is extremely helpful in an early phase of their career. Although cross-CRC initiatives are supported by the ERS, official applications must still be submitted to the respective programmes (figure 2). Importantly, CRCs represent unique opportunities to

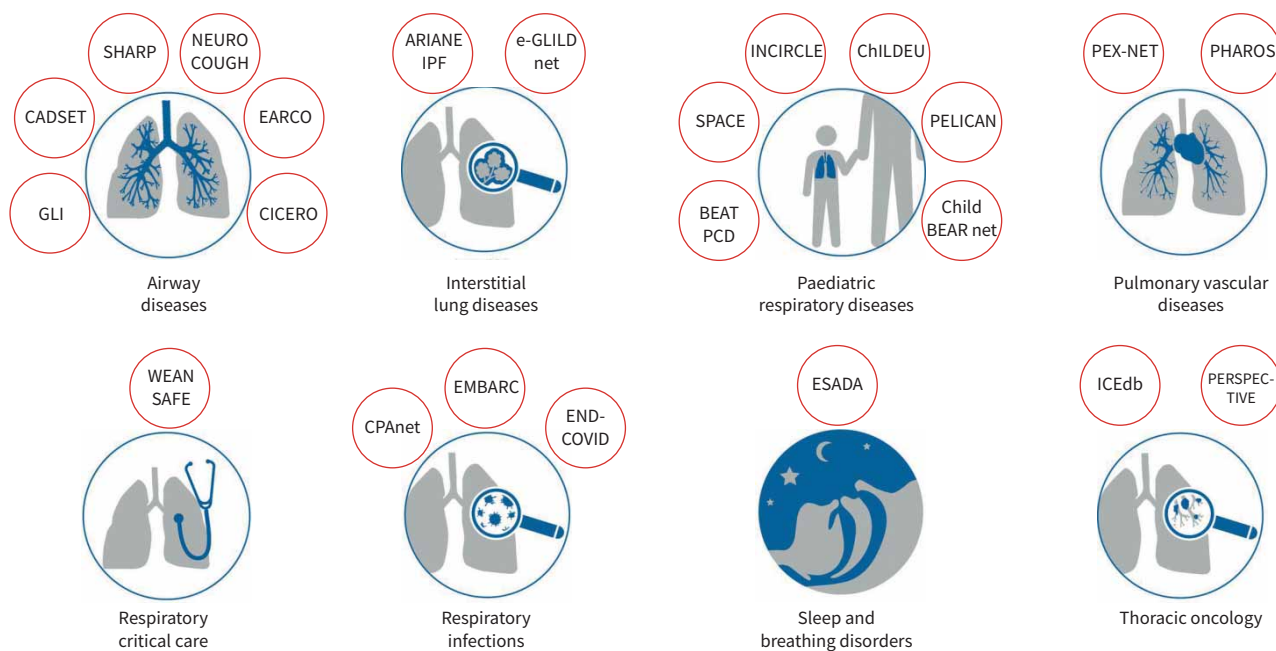


FIGURE 1 Mapping of the European Respiratory Society Clinical Research Collaborations onto the eight main respiratory disease areas.

collect real-life data on various clinically important issues. As such, they can usefully provide supportive evidence to task forces developing official ERS scientific documents, including clinical practice guidelines [4]. Patients’ input is crucial in this regard. In addition, CRCs often represent opportunities to define formally the items to be collected for research in the clinical situations on which they focus, based on detailed appraisals of the literature and experts’ opinions, and also including patients’ input [5]. These may

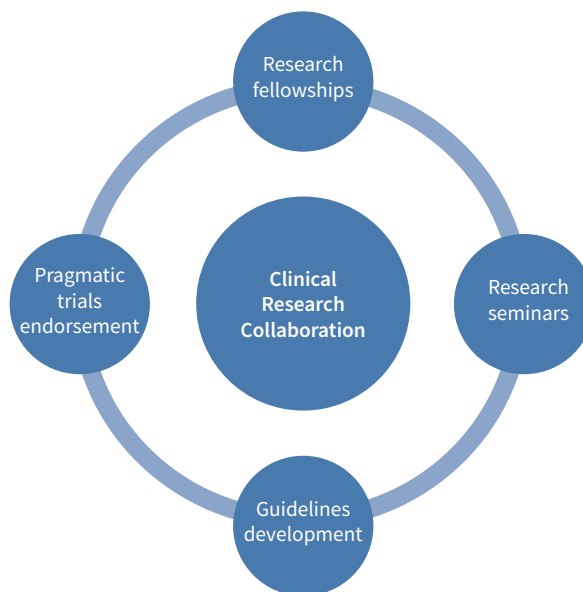


FIGURE 2 Connection of the Clinical Research Collaborations with other European Respiratory Society (ERS) activities: research seminars, development of guidelines, pragmatic trial endorsement and research fellowships. Official applications to the respective ERS activities must still be submitted.

also be the topic of ERS official documents. Finally, data collected by CRCs can be used to assess how guidelines are implemented and what their clinical impact is. These are only a few examples of the multiple types of interactions that can occur between ERS CRCs and task forces.

Clinical research applications can be submitted annually by 15 October. Each CRC receives funding for a 3-year period, and after this can apply for an additional 3 years, making a total of 6 years' seed funding to build a network, set up plans and launch activities. Thereafter, successful CRCs can apply for continued ERS badging as a CRC but without additional funding from ERS. Since ERS does not have the financial means to provide substantial funding to conduct research or clinical studies, external funding is often sought from EU funding programmes and/or other funding agencies. Industry partnerships with CRCs are encouraged where considered appropriate and beneficial for the delivery of the aims of the CRC. In 2018, the ERS Research Agency introduced a three-tier model, which is explained as follows. When the CRC is endorsed, three different tiers/layers of ERS Research Agency engagement can be chosen by the CRC chairs (figure 3). In tier model 1, the CRC runs the project independently of the ERS Research Agency. Financial support is provided, but the ERS Research Agency is not involved in the project. In tier model 2, the ERS Research Agency supports the CRC to obtain additional funding needed to deliver and achieve its major objectives. The ERS Research Agency provides operational and project management support. In case of collaboration with funding partners, negotiations and contracting activity are coordinated by the ERS Research Agency. As per ERS policy, contribution from a minimum of two different funding partners is required to avoid the CRC being dependent on one company. This model has been shown to be effective and appreciated by both researchers and industry partners. Several CRCs have successfully obtained research funding. In case funding is obtained, the CRC automatically moves to tier model 3, where the ERS Research Agency ensures that the timelines and deliverables agreed are met and funds adequately used.

Within the current ERS CRC portfolio, there are five CRCs operating in tier model 1, 11 in tier model 2 and seven in tier model 3. As shown, several CRCs have been successful in obtaining sustainable funds for research, including EMBARC [6], SHARP [7], CADSET [8], NEuroCOUGH [9], EARCO [10], CICERO [11] and END-COVID. Between February 2015 and May 2021, more than EUR 9.6 million has been invested by external funders within the CRC programme and we are targeting a steady income of EUR 2 million per year for the coming 3 years. During this period, there has been a commensurate increase in ERS Research Agency staff to support the CRC programme. One of the most recent CRCs in tier model 3 is Collaboration In COPD ExacerbatiOns (CICERO) [11]. CATALINA is the flagship study

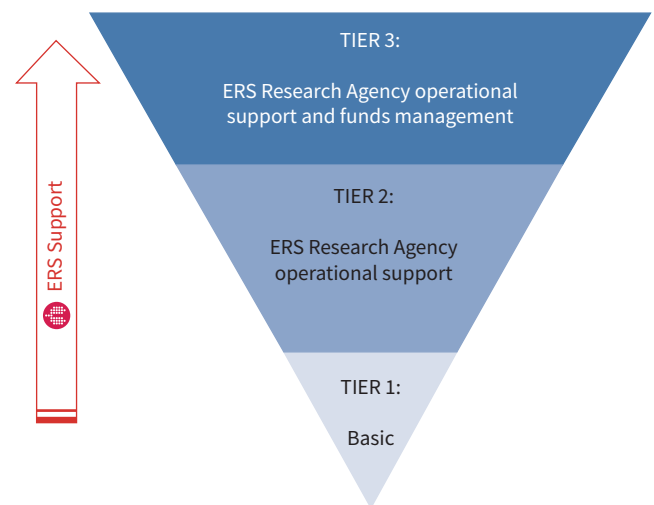


FIGURE 3 European Respiratory Society (ERS) Research Agency three-tier model for Clinical Research Collaborations (CRCs). Tier model 3: external funding obtained by the CRC together with broader role of the ERS Research Agency. Tier model 2: ERS Research Agency supports the CRC to obtain additional funding and provide basic operational support. Tier model 1: the CRC runs independently of the ERS Research Agency.

of the CICERO CRC. CATALINA is a prospective observational cohort study designed to recruit 2000 patients hospitalised for acute COPD exacerbations with longitudinal follow-up. Along with extensive clinical characterisation including clinical, functional and imaging data, samples from sputum and blood will be collected at fixed time-points. This unique data collection and biobank will be used to define phenotypes of COPD exacerbations and identify clinical fingerprints and specific biomarkers to guide future improved and more personalised treatments. The CICERO CRC will be a collaborative effort from expert centres across Europe. As applies to all CRCs, investigators capable of following the approach and industrial partners eager for innovation, are welcome to join and are invited to contact the chairs [5].

In conclusion, the ERS CRCs address clinically important research areas across all major respiratory disease domains. The ERS Research Agency supports the CRCs, and ensures links with other ERS activities; the recently introduced three-tier model has proved to be successful in obtaining significant funding, allowing extension of clinical and translational research ambitions. The future challenge for the programme lies in ensuring sustainable funding for successful CRCs beyond the initial phase and the ERS-funded period, and in finding pathways for research areas currently underfunded.

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