

Guidance for the development and conduct of ERS Clinical Research Collaborations (CRC)



Table of Contents

Table of Contents.....	- 2 -
1 Introduction.....	- 3 -
2 Definitions	- 3 -
2.1 ERS CRC.....	- 3 -
2.2 Patient and public input	- 3 -
2.3 Development and dissemination of novel research protocols.....	- 4 -
3 Application and approval process	- 4 -
3.1 Online Platform	- 4 -
3.2 Application review and triage process	- 5 -
4 Project Development	- 6 -
5 Dissemination and communication.....	- 7 -
6 Rules for CRCs.....	- 7 -
6.1 CRC Governance	- 7 -
6.2 CRC Composition	- 7 -
6.3 Funding.....	- 8 -
6.4 CRC Link person	- 8 -
6.5 CRC Tier Model: Funding partners engagement and ERS Research Agency	- 9 -
6.6 Duration of support.....	- 12 -
6.7 Reports	- 14 -
6.8 Regulatory and ethical issues	- 15 -
6.9 Meetings.....	- 15 -
6.10 Joint CRC with other organisations.....	- 16 -
6.11 Promotion.....	- 16 -
6.12 Liability	- 16 -
6.13 Intellectual property.....	- 16 -
6.14 CRC assets sharing	- 16 -
7 Appendix 1 - CRC online application: Checklist of the requested fields/documents	- 17 -



1 Introduction

The European Respiratory Society (ERS) contributes to the coordination of research activities in respiratory medicine across Europe, by encouraging new initiatives, producing guidelines, supporting and disseminating information, developing joint documents with other major associations and/or international scientific societies, and other research activities including partnerships with Industry Partners.

ERS may support the work of a Clinical Research Collaboration (CRC) in areas of respiratory medicine where a pan-European multi-centre network of principal investigators aims to advance clinical and translational research. It may also integrate non-European countries as well as non-ERS members, representing different scientific disciplines which complement the network with multispecialty, multidisciplinary and multifunctional know-how and expertise.

If the application is successful, the CRC is expected to follow the ERS rules as described in Chapter 6.

2 Definitions

2.1 ERS CRC

The aims of an ERS CRC are to promote the exchange of research ideas among clinicians and affiliated scientists in Europe and/or globally; to plan, conduct, evaluate and publish clinical and translational studies; to gain eligibility for network funding; to build an infrastructure for prospective clinical research and to agree on standardised approaches to address specific research needs. Outputs of an ERS CRC would typically be scientific products, such as original articles for publication in scientific journals or abstract submission for presentation at scientific congresses.

For CRCs to ultimately become self-sustaining, a strategy to secure inward investment in the longer term is encouraged and may include approaching relevant grant funders at a local country level, Industry partners, or for example, seeking European Commission funding. However, ERS recognises that inward investment may not be possible for selected CRCs depending on the respiratory research field.

Approved ERS CRCs are not legal entities. ERS aims to endorse projects under the current CRC rules and facilitate CRCs' developments. ERS CRCs are embedded in ERS activities and projects.

Clinical studies are health-related research studies in humans that follow a pre-defined (research) protocol. Multicentre research studies proposed by the CRC can be observational or interventional, prospective or retrospective. The types proposed can assess any combination of treatment, prevention, diagnostic, screening, health economics, implementation or quality of life studies. These studies can provide a better understanding of the disease, including treatments and clinical practice patterns by generating innovative, new or alternative interventional and practice approaches.

2.2 Patient and public input

The ERS Science Council recognises that patient and public input into CRCs is important, strongly encouraged, and likely to help to:

- Underpin the activities and outputs of the collaboration with patient experience.
- Ensure that the work of the CRC addresses key issues of concern to patients or that may have been overlooked by healthcare professionals.
- Build on the real-world experience of patients to ensure that proposed clinical studies and trials are feasible and acceptable to patients, and are likely to influence clinical practice.
- Develop patient-facing material for example leaflets, brochures or web content to support patients living with respiratory diseases.
- Provide input from individuals across Europe to ensure that factors, such as access, equity and cost, are taken into account.



- Optimise patient access to, and support for, the resulting outputs of the CRC.

The European Lung Foundation (ELF; www.europeanlung.org) would welcome contact from any CRC chairs keen to investigate ways in which patient input could enhance their work. ELF has a long experience in coordinating patient engagement and an established network of patient organisations and Patient Advisory Groups with members from across Europe, who are keen to support CRC activities. Options include patient input into research priority-setting, patient representatives joining the CRC steering committee (e.g. Patient Chair or steering committee member), patient input into clinical study design and outcome measures, patient review of participant information sheets, consent forms and ethics documentation, patient consultation (including surveys and focus groups), patient input into governance and ethics discussions, and the development of a patient version of outcome documents.

To understand the levels of support available from ELF, please read section 6.5 *CRC Tier Model*.

To discuss possible options for patient input, please contact ELF - Patient involvement and engagement department (info@europeanlung.org). Find out more about ELF's patient input process on their website (<https://europeanlung.org/en/about-us/our-patient-input-process/>).

2.3 Development and dissemination of novel research protocols

The CRC should decide on **priority research questions** related to where there is an unmet medical need, and where there is a need to gather real world evidence/data in a multi-centre research study. Based on the identified questions, the CRC will develop and share new research protocols on clinically orientated topics of the relevant disease area and lead the development of priority research projects in the field.

Each year, the ERS Science Council identifies key areas where there are potential research gaps in the CRC portfolio by providing a '**highlight notice**' and encourages proposals in the identified topic(s). Highlight notices topic(s) are developed after consultation with each ERS assembly, aligned (where possible) to future funding calls from the European Commission and are ratified by the CRC Working Group. The Highlight notice(s) are advertised on the [CRC website](#) when the CRC application programme call is announced to be open in July each year.

The ERS CRC programme encourages any proposals which could **foster synergies between the CRCs** and the discussion upfront with existing CRC Chairs and CRC Director is highly encouraged before preparing an application in order to avoid any overlap within the research activities of existing CRCs. Details of the CRC portfolio including available information of ongoing CRCs can be found on the CRC website (<https://www.ersnet.org/science-and-research/ongoing-clinical-research-collaborations>). If you wish to discuss/contact the CRC Director and/or CRC Chairs, please contact the ERS Office (scientific@ersnet.org) and you will be directed to the appropriate persons to initiate the discussion.

3 Application and approval process

All CRC proposals are evaluated on scientific excellence and potential impact. The CRC proposals aim to describe the purpose and structure of the CRC and show how the objectives will be achieved. The CRC proposals can be submitted by several ERS members belonging to one or more scientific assembly(ies)/group(s).

3.1 Online Platform

Applications and all supporting documentation should be submitted in English and online *via* the ERS CRC application platform (<https://www.ersnet.org/research/clinical-research-collaborations>). The web browser Google Chrome is advised to be used for a smooth fill in of information and upload of all documents.

The application is considered as complete when it contains:

- The CRC online application form is duly filled. The application should include the three mandatory deliverables:
 - Year 1: established Governance model.



- Year 2: Research agenda summarised in a published editorial/article.
- Year 3: Detailed project implementation plan including funding strategy and budget

(Appendix 1 - CRC online application: Checklist of the requested fields/documents for the description of requested fields).

1. One page CV with the 5 main relevant publications of both Chairs, justifying their expertise in the field and their role/responsibility in the CRC proposal.
2. The annual Declaration of Interest (DoI) signed by both Chairs. This document will be requested by the ERS Office through the myERS platform after the submission deadline.
3. A 90-second elevator pitch video explaining the main objectives, how they will be achieved and how they will benefit the respiratory community and patients. We suggest creating a MP4 video in PowerPoint. Instructions on how to create such a video can be found [here](#).

The deadline for submitting applications and documents is 15th of October each year without extension.

3.2 Application review and triage process

Each application will go through the following evaluation and approval process:

1. An administrative check for the completeness and eligibility will be conducted for all received CRC applications by the ERS Office.

A CRC proposal is considered as eligible to be sent for peer-review if the below selected criteria are met:

- The application is complete.
- The project membership is multicentric and international. Significant participation of European countries is expected. Participation of institutions based outside of Europe can be included.
- It focuses on disease areas of respiratory medicine or related issues.
- The objectives and ambitions of the proposal is to develop a work programme and does not restrain itself to a single clinical study or trial.
- At least one of the Chairs is an ERS member.

The project membership diversity i.e. the inclusion of patient(s) or carer representative(s), ERS early career members (<40 years old), gender balance (see ERS Diversity and Inclusion policy: <https://www.ersnet.org/ers-diversity-and-inclusion>); Equity, Diversity and Inclusion (EDI) is considered an asset for the proposal but will not prevent the application from being considered eligible if only this last point is not met. Please refer to section 6.2 *CRC Composition* for additional details.

The ERS CRC Director is entitled not to send a proposal to peer-review, should any of these criteria not be fulfilled.

2. The ERS Office will select a minimum of two independent reviewers, who are members of the CRC Working Group, to comment on the content of the application. The ERS CRC Director (and/or Director elect, if applicable) - will review all applications received.
3. All reviewers will be asked to notify the ERS Office (In writing *via* e-mail) if there is a direct conflict of interest. This might include for example, working at the same Institution as a CRC Chair, being part of the leadership group of a CRC, or any other perceived direct conflict of Interest. It should be noted that indirect conflicts of interest are common in large network proposals and will not preclude review of a CRC application. If a reviewer is deemed to be directly conflicted, an alternative reviewer will be sought by the ERS Office.



4. The reviewers will evaluate the eligible CRC proposals against the following criteria:
 - **Scientific excellence** (30%) of the proposal and the specific contribution that the CRC will offer to the respiratory community.
 - **Deliverability** (30%): The likelihood that the core deliverables of the CRC can be met in the stated timelines. Any plans to obtain sustained external funding and rationale for the use of ERS funding requested.
 - **Program Management plan** (20%), leadership, project membership diversity, management, and governance arrangements for delivering the CRC proposal.
 - **Risk mitigation** (10%) clearly stated risks and their mitigations linked to the core deliverables of the CRC.
 - **Patient involvement** (10%), and where relevant ELF engagement in the proposal outline/planned prospective engagement if the CRC is awarded.
5. ELF will also review the applications for the level and appropriateness of patient involvement. Patient reviewers may also be consulted during the reviewing process. When patient involvement has not been included, ELF may suggest at the review stage how patient involvement could benefit the CRC and propose ways of involving patients.
6. CRC proposals addressing a 'highlight notice' topic(s) will follow the same scoring and reviewing process as the other applications. These proposals will not be favoured during the review process but for applications evaluated of equal excellence (i.e. equivalent scores and votes), topics including highlight notices would be prioritized.
7. Based on the reviewers' assessment which will include the triage scores and any associated feedback from ELF, the ERS CRC Director will validate the list of proposals for discussion with the CRC Working Group; for the threshold for being awardable will be set according to 1) the quality of the applications received and 2) the number of allocated funds by ERS.
8. Triage scores of all proposals will be presented at the CRC Working Group meeting alongside a summary of the awardable CRC proposals for CRC funding by the CRC Director and with input from the proposal peer reviewers. The proposals are discussed in two categories: 1) highlight notice(s) and 2) new proposals - and from highest to lowest score in each category. The CRC Working Group will be reminded of their duty of confidentiality to ERS during this meeting.
9. The CRC Working Group will then vote on the triaged proposals to be selected for prioritisation and funding, with those proposals that achieve the highest median score and most of the votes being put forward.
10. The ERS Science Council decides based on the recommendation of the ERS CRC Director on approval or rejection of the CRC applications. It may request scientific and logistical changes to the awarded proposals as appropriate. The ERS Science Council may also make recommendations on membership of the CRC.
11. The ERS Science Council decision has to be finally endorsed by the ERS Executive Committee.

The time taken for the reviewing and approval procedure may vary and takes around four (4) months (until February of the following year) for a decision. The applicants of successful and unsuccessful CRC proposals will receive a notification letter by email.

4 Project Development

For all approved CRC proposals, a kick-off teleconference will be organised with the CRC Chairs, the CRC Director, a nominated CRC Link person and a member of the ERS Office in order to describe the terms and conditions linked to their CRC, discuss logistic aspects, and, eventually, funding and supplementary



background materials prior to the start of their projects. ELF will approach CRC Chairs to discuss plans for patient involvement following the kick-off teleconference, if relevant.

CRC Chairs will be asked to sign a CRC agreement to settle the terms of collaborations between ERS and the CRC Chairs.

Annual reporting is expected to the ERS CRC Director and CRC Working Group to assess project advances according to the CRC agreement and to review the *per annum* budget spent (section 6.7 Reports). Any substantive changes in the goals, strategy or the budget of a CRC must be reported to the ERS Office at any time and should be approved by the ERS Science Council.

All official ERS policies including those on travel, publications, conflicts of interest, CME, and others must be followed during all phases of the project. Failure to comply with these will result in immediate withdrawal of ERS support. The ERS CRC Director and the ERS Science Council Chair will inform the ERS Secretary General who will act accordingly.

5 Dissemination and communication

Results of CRCs should lead to manuscripts for publication in relevant peer-reviewed scientific journals. Submission to an ERS journal, such as the European Respiratory Journal (ERJ), are encouraged and will be subject to the normal procedures for peer review.

If during or after the research project, the CRC steering committee considers the development of Guidelines, Statements, or Technical Standards relevant to the CRC topic, then, an official application through the ERS Task Forces funding scheme, under the supervision of the ERS Guidelines Director, should be submitted.

Preliminary results from these clinical research studies may lead to submission of abstracts for presentation at scientific congresses and submission for presentation at the ERS International Congress is encouraged.

ERS encourages CRC networks to produce content for the [ERS Respiratory Channel](#) to support dissemination of the project results. The ERS Office should be contacted.

Note that any statement or other official communication in the name of ERS must be approved by the ERS Executive Committee before publication.

CRCs are encouraged to consider how to communicate their outputs to patients and the public, for example, through the production of a lay summary or factsheet to accompany a scientific publication. ELF can support the production of patient-facing materials. Please also view the section 6.3 Funding.

6 Rules for CRCs

6.1 CRC Governance

The CRC should be governed *via* its own steering committee, which should be composed of the CRC Chairs, academic ERS members and any other non-member academic stakeholders. Patient representatives could be members of the CRC steering committee. The CRC steering committee refers to their nominated CRC Link person and the CRC Director who, supported by the CRC Working Group, reports to the ERS Science Council.

6.2 CRC Composition

A CRC is a multidisciplinary research network and is expected to be primarily composed of principal investigators who are ERS members. The initiative should represent a significant proportion of pan-European countries to ensure a wide perspective and representativeness. The presence of ERS early career researchers (< 40 years old), the gender balance (see [ERS Diversity and Inclusion policy](#)), Equity, Diversity and Inclusion (EDI), as well as patient representatives is strongly encouraged.



It may also integrate non-European countries as well as non-ERS members, representing other scientific disciplines which would complement the network with multispecialty, multidisciplinary and multifunctional know-how and expertise. CRC members can join the project later whenever deemed necessary or suitable.

After six (6) years that a CRC is running, the ERS Science Council would encourage to revise (where relevant) the CRC Chairs/ core Leadership to promote emerging leaders and include new perspective to the CRC. The CRC membership diversity as mentioned above (ie. ERS early career researchers, gender balance, EDI, patient representatives), must be engaged. A succession strategy plan and progress status will be requested in the annual progress reports (section 6.7 Reports).

6.3 Funding

The ERS CRC funds for CRCs is not to be considered as an ERS grant; it is funding that ERS has earmarked for up to a three (3)-year period for routine expenses during project development. The approved CRCs will be funded up to 15,000 Euros (€) per year by ERS for a maximum of three (3) years, allocating a total budget of 45,000 Euros (€), with the possibility of receiving additional 15,000 Euros (€) during the 1-extra year (section 6.6 Duration of support and 6.7 Reports).

Allocated funds by ERS will be administered by the ERS Office in Lausanne according to the terms of the CRC agreement. All expenditure charged to the ERS project accounts must be approved by the ERS Office in advance. For the use of the ERS CRC funding regarding meeting expenses, refer to section 6.9 Meetings.

The release of the *per annum* ERS CRC funds is dependent on successful review of the annual progress report (section 6.7 Reports). The allocated ERS CRC funds cannot be used to cover ERS dissemination activities. If during the conduct of the research project, educational activities (including webinars), online scientific workshops, or other ERS dissemination methods are thought to be relevant, a separate application through the appropriate scheme would be necessary.

ERS does not have the financial means to fund the research or clinical studies and/or trial that the network intends to conduct. If appropriate and relevant, grant applications for research and/or network funding should be submitted to the EU and/or other funding agencies with the aim of funding the activities of the CRC.

ERS provides independent funding to ELF to facilitate patient involvement at a basic level. However, patient participation to CRC meetings has to be funded by the ERS CRC funds and sufficient budget should be considered.

ELF may also facilitate patient involvement at a higher level but there are charges for this. See '[ELF Levels of Involvement](#)' to see what patient input activities can be covered and the likely costs (e.g. creation of patient surveys). These higher levels of support from ELF may be a more realistic option when external funding is secured (e.g. industry, academic grants).

Please note that ELF has limited capacity to support CRCs at a higher level and decisions on support available will be discussed with each CRC.

6.4 CRC Link person

Once the CRC is endorsed, a member of the CRC Working Group is nominated by the CRC Director as a CRC Link person and will have the responsibilities outlined below towards the CRC project:

1. Provide close support to the CRC research project during the first year at the initial/set-up stages of the project.
2. Oversee the CRC project advance and delivery according to the CRC proposal.
3. Provide insights, problem solving support, and facilitate the CRC progress.
4. Link for any potential collaboration with other CRCs.
5. Provide feedback to ELF on patient engagement.



6. Review the CRC annual progress reports and evaluate progresses compared to the initial CRC application and/or previous CRC annual progress reports.
7. Provide any recommendations or highlight any corrective actions to be taken if deemed necessary.
8. Report to CRC Director and/or the rest of the CRC Working Group any potential CRC project issues or risks to be raised at any project stage.

CRC Chairs should liaise with the CRC Link person throughout the duration of the CRC for any type of support and invite him/her to join teleconferences for project progress status that the CRC Chairs may have with the rest of the CRC project.

CRC Chairs can meet face-to-face with their CRC Link person during the ERS International Congress.

Note that the CRC Link person should not have a conflict of interest (CoI) with the CRC project.

6.5 CRC Tier Model: Funding partners engagement and ERS Research Agency

When the CRC project is endorsed, three (3) different tiers/layers of ERS engagement can be applied by the CRC Chairs. The level of engagement is mainly related to additional fund-raising activities and involvement of the ERS Research Agency.

Industry partnerships with CRCs are encouraged where considered appropriate and beneficial for the delivery of the aims of the CRC. In case of Tier 2/3 and to ensure coordination between CRCs and other ERS initiatives and industry, the partnerships must be discussed with the CRC Director.

In case of engagement with Industry, ERS would act as Neutral broker between the industry partners and the CRC consortium which includes the below characteristics:

- Transparency
- Inclusion
- Agreed benefits
- Agreed milestones
- Reporting
- Control of funding

Transition from one tier to the next level is possible depending on the development of the CRC project.

Any exceptions to the conditions laid out in each tier (for example where an existing set up makes it difficult to fully agree to all conditions) should be agreed by the ERS Science Council Chair and CRC Director and made clear to the concerned parties.

TIER 1	
Goal	Provide financial support to the set up and/or maintenance of a CRC research network where the researchers wish to receive seed funding from ERS but wish to run the project independently of the ERS Research Agency.
CRC Funds	The CRC funds would be held and managed by the ERS Office to cover the expenditure mentioned in the CRC proposal.
Conditions	<ol style="list-style-type: none"> 1. CRC Chairs are responsible for ensuring the approved budget is not over-spent. 2. Salary expenditure could be anticipated for administrative staff, NOT for expert stakeholders involved in the project.



	<ol style="list-style-type: none"> 3. ERS Office is not involved in the conduct of the project. ERS cannot be held responsible for any actions taken by the CRC research network. In case of litigation, ERS is not liable. 4. For any current or future collaboration with any third-party funders independently of the ERS Research Agency (i.e. pharmaceutical and medical device companies, other medical or research societies, foundations...), the CRC Chairs cannot claim to be an ERS Research Agency supported CRC but should state they have received a financial support from ERS to support their project. 5. ELF ensures basic services linked to patient involvement in the project. See ELF Levels of involvement for further details.
TIER 2	
Goal	Bring a CRC research network to a status where they are able to obtain through the support of ERS Research Agency substantial funding needed to deliver and achieve major objectives of the CRC.
CRC Funds	The CRC funds would be held and managed by the ERS Office to cover the expenditure mentioned in the CRC proposal.
Conditions	<ol style="list-style-type: none"> 1. In case of collaboration with funding partners, negotiations and contracting activity will be coordinated by the ERS Office. <ol style="list-style-type: none"> a. As per ERS policy, contribution from a minimum of two different industry companies is expected. b. All external funding for the CRC will be collected and managed through the ERS Office with a retention of 10-percent (10%) from the industry funds spent to cover the costs of the ERS Office for its neutral broker role as described in section 6.5. c. The CRC Chairs will lead the discussions on the scientific content and the ERS Office will lead the contractual and financial matters. d. The CRC Chairs will have to provide a milestones-based project summary including benefits offered to funding partners, a description of the governance structure, a data access policy, a publication policy, as well as a detailed budget and a plan how the budget will be used. This will have to be approved by the ERS Office, the ERS CRC Director and the ERS Science Council Chair. e. The CRC Chairs should always involve the ERS Office in their contact with potential funders and particularly the industry to ensure there is one single communication channel through the ERS Office regarding funding and all other terms of the contractual agreement. f. In case contractual relationships are already in place, this condition could be submitted to modifications. g. Any new contractual agreement with funding partners will be between ERS and the funding Partner only and the application for funding will follow the agreed process set out by the ERS Office. h. The same conditions apply for any funding partner. However, the requirements of the different funders need to be taken into consideration during the negotiation period.



	<ol style="list-style-type: none"> 2. The CRC should not start incurring costs outside of the 15,000 Euros per year (45,000 Euros in total) original ERS CRC funding agreement until the contracts with the funding partners for the wider projects outlined by the project summary have been finalized. 3. ERS would provide through the ERS Research Agency basic operational and project management support i.e. organise regular TCs and meetings, support in setting up documentation (project plans and budgets) and monitoring project delivery, suggest service providers, ensure links with other CRCs or ERS research activities (e.g. congress, online scientific workshops, fellowships, task forces...). This will be adapted depending on the needs of the projects. 4. Additional responsibilities of the ERS Research Agency would be negotiated on a per project basis, before starting the negotiation process with funding partners and have to be covered by the additional CRC funds. 5. Funds can be used to develop a website for the CRC and a project specific logo to reflect its own identity. Project-specific website could be managed through ELF if sufficient funding is available, and ELF has capacity. 6. The CRC should recognise ERS for its financial support on all material, presentations and publications. Use of ERS logo needs to be approved in advance by the ERS Office. 7. Meetings can be organized through the ERS Office on request (<i>see section 6.9 Meetings</i>). 8. ELF ensures basic services linked to patient involvement in the project - plus further activities for an additional cost. Any activities / tasks you would like ELF to facilitate should be discussed and agreed upfront with ELF, the CRC Chairs and the ERS Office following the CRC kick-off teleconference and that direct and indirect costs shall be covered by the CRC funds if deemed necessary. ELF will submit a detailed plan and budget that would need approval of the CRC Chairs and the ERS Office. See ELF Levels of involvement for further details.
TIER 3*	
Goal	<p>To ensure that the timelines and deliverables agreed with the funding partners are met as well as the adequate use of the funds.</p> <p><i>*This model is only applicable once relationship with funding partners is established. Therefore, this model is not applicable at the time of the endorsement of the CRC.</i></p>
CRC Funds	The CRC Funds AND the additional external Funds received from funding partners would be held and managed by the ERS Office.
Conditions	<p>The following additional conditions from Tier 2 enter into forces:</p> <ol style="list-style-type: none"> 1. The ERS Office will collect and manage funding for the CRC and will retain 10-percent (10%) from the funds received from funding partners to cover the costs of the ERS Office for its neutral broker role as described in section 6.5. 2. ERS could have a broader role in the CRC through the ERS Research Agency mainly in project management to ensure that sub-projects activities are met - outside of overall contract requirements with fund providers. This should be covered by the additional external funds received from funding partners.



	<ol style="list-style-type: none">3. The CRC Chairs will have to comply with the conditions of the collaboration agreement with the Funding Partners, in terms of the milestones, objectives of the project, access to data and reporting terms.4. The allocation of the additional external funds is decided by the CRC Chairs. Involvement of external consultants should be approved by ERS and be limited to tasks that could not be performed by the CRC Chairs, CRC members, ERS early career members, ERS Office or academic institutions. Involvement of external consultants should be kept to the minimum and supported by good arguments.5. The allocated funds from funding partners CANNOT be used for the payment of the salary of expert stakeholders (i.e. CRC Chairs, principal investigators) and patients representatives for their involvement in the project. However, the funds could be used to cover the operational staff costs (e.g. Ph.D students, biostatistician, data scientist...) involved for the completion of the CRC tasks defined in the budget plan.6. The allocated funds from industrial funding partners CANNOT be used for the development of Guidelines, Statements, or Technical Standards.7. The ERS Research Agency will set up the appropriate separated contracts with the participating academic institutions/partners for the contribution to the expenses in relation to the CRC tasks defined in the budget plan. ERS is a non-for-profit organisation and recommends to each participating institution to not apply overheads or limit overheads to a maximum 20% rate.8. Any change from the originals plans especially to the milestones and deliverables, the budget and the plan on how to spend it as well as the funding partners benefits have to be discussed with the ERS Office, the CRC Director and the ERS Science Council Chair prior to implementation.9. ELF ensures basic services linked to patient involvement in the project - plus further activities for an additional cost. Any activities / tasks you would like ELF to facilitate should be discussed and agreed upfront with ELF, the CRC Chairs and the ERS Office and that direct and indirect costs shall be covered by the additional external funding. ELF will submit a detailed plan and budget that would need approval of the CRC Chairs and the ERS Office. See ELF Levels of involvement for further details.
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6.6 Duration of support

The approved CRCs will follow different phases of funding with the applicable conditions:

- **Initial ERS CRC funding support:** The proposed CRCs would be financially supported by ERS for an initial duration of three (3) years, based upon the deliverables defined in the CRC agreement.
- **One (1)-extra year WITH ERS CRC funding support request:** When the CRC has reached the end of the 3-year funding period AND in case it has experienced delays in the implementation of its objectives linked to long-term sustainability, the CRC is eligible to request for an additional year WITH ERS CRC funding (ie. 15,000€).

The request for the 1-extra year of ERS CRC funding is managed through the annual progress report process at the end of the 3-year funding period i.e., **late March** (see clause 6.7 Reports). The request for 1-extra year is not competitive but is subjected to the following criteria:

- The outcome of the annual progress report of Year 3 must be good.
- Project delays will only be considered acceptable if it is related to the sustainability objectives.
- At least 50 percent (50%) of the ERS CRC funds shall be spent.



- No major Industry support/country-level grants should have been secured.

For reviewing process, please refer to section 6.7 "reports".

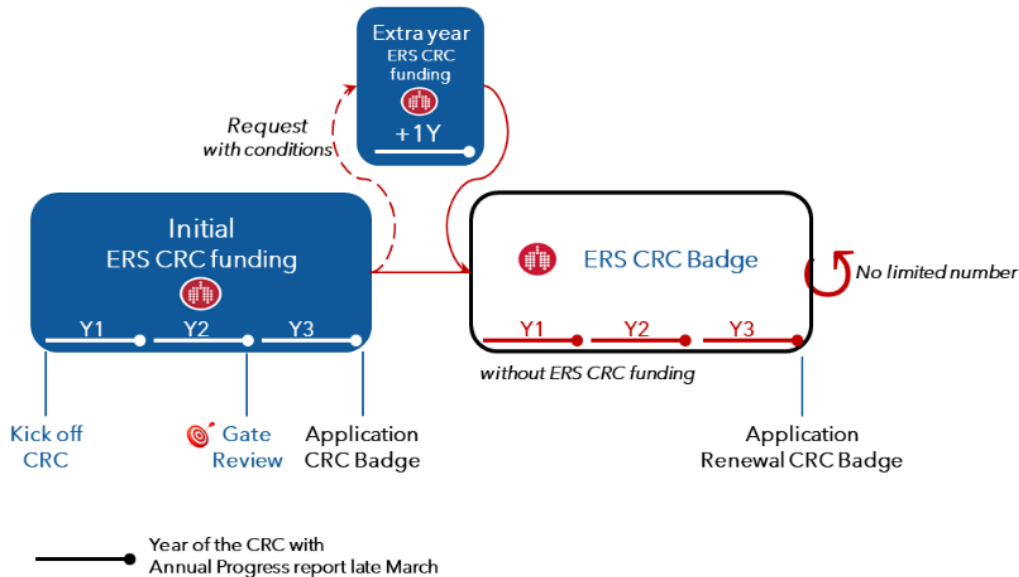
In case any of the above-mentioned criteria is not met, 1-extra year WITHOUT ERS CRC funding support, could be granted allowing access to the benefits linked to CRCs (e.g., section 6.9 *Meeting facilities* and 6.11 *Promotion*) for an additional year.

- Applying for the "ERS CRC Badge" WITHOUT ERS CRC funding support: When the CRC has reached the end of 1/ the initial 3 years ERS CRC funding period or 2/ the 3+1 year ERS CRC funding period, the CRC Chairs could apply for the "ERS CRC Badge" allowing access to the benefits linked to CRCs (e.g. clause 6.9 *Meeting facilities* and 6.11 *Promotion*) for an additional three (3) year period. In such case, the CRC rules continue to apply especially the clause 6.7 *Reports* and 6.12 *Liability*.
 - The first "ERS CRC Badge" application is managed through the annual progress report process at the end of the ERS CRC funding period i.e. **late March** (see clause 6.7 *Reports*).
 - Reviewing criteria measuring the success of the CRC in the previous period and the relevance of project continuation may be used in order to approve the granting of the "ERS CRC Badge". Therefore, the CRC Chairs should underline the expected future developments, the plans to make the CRC sustainable and a suitable succession planning for the next three (3) year period.
 - If interested, the CRC Chairs could apply for the renewal of the "ERS CRC Badge" at the end of each three (3) year period without a limited number of renewal applications.
 - For reviewing process, please refer to section 6.7 "Reports".
- End of ERS CRC funding period:
 - At the end of the ERS CRC funding period, any left-over of the CRC funding that has not been allocated will be retrieved back to ERS even if the CRC is granted with the "ERS CRC Badge" for the next additional period of three (3) years. If any exceptions should occur according to the CRC situation and respective plans, this needs to be indicated in the last progress annual report and reported to the ERS Science Council.
 - If the CRC is not granted with the "ERS CRC Badge", then ERS will terminate the CRC and will remove all the benefits linked to CRCs. If applicable, any left-over budget will be cancelled and retrieved back to ERS.



The below figure describes the different life-courses of a CRC with ERS CRC funding support or "ERS CRC Badge".

CRC lifecourse with ERS CRC funding or ERS CRC Badge



6.7 Reports

The CRC Chairs will provide an annual progress report, explaining 1) the achievements and completion of expected deliverables or any deviation from the initial plans, 2) their sustainability and succession planning strategies, 3) the patient engagement strategy and 4) a detailed description of the expenses, to be sent to the ERS Office (scientific@ersnet.org) usually **late March each year**. The reports of the CRCs that are in their 3rd year will include requests for "1-extra year funding" and for "ERS CRC Badge".

- The CRCs that are terminating their 2nd year ERS CRC funding period, have to comment on the following mandatory deliverables:
 - Year 1: established Governance model.
 - Year 2: Research agenda summarised in a published editorial/article.
 - Year 3: Detailed project implementation plan including funding strategy and budget

Gate review at Year 2: The CRC Working Group members will assess the progress of the CRC against the first two mandatory deliverables and in case the deliverables have not been met CRC termination could be discussed.

- After the first "ERS CRC Badge" cycle, this badge can be renewed where additional reviewing criteria may be used to measure the success of the CRC and the relevance to maintain the "ERS CRC Badge" each year. These CRCs are expected to produce at least 2 publications this period (no editorial/review) OR 1 publication in a journal with an Impact Factor > 10 in order to keep the "ERS CRC Badge" the following year. This criterium shall not constitute an exclusive criterium, however the reasons why if it has not been met should be indicated to the CRC Working Group for evaluation.

Report assessment process will run as follows:



- The annual progress report including the 1-extra year of ERS CRC funding request and "ERS CRC Badge" request will be forwarded to the CRC Link person, the CRC Director (and CRC Director-elect if applicable) and ELF to assess and comment.
- Based on the reviewer's assessment and any associated feedback from ELF, the ERS CRC Director will validate the list of CRCs to be discussed at the CRC Working Group meeting.
- The CRC Working Group will be asked to discuss and provide recommendation on the following cases:
 - CRC for which concerns have been raised by the reviewers
 - 1-extra year of ERS CRC funding request
 - "ERS CRC badge" request
 - CRC having terminated their 2nd year of funding = Gate Review
- The CRC Working Group will then vote on the recommendation for the termination of a CRC and/or the rejection/approval of a request.

The progress status of all running CRCs and recommendation made by the CRC Working group will be reported to the ERS Science Council. The release of the *per annum* ERS CRC funds or the continuation of the "ERS CRC Badge" are dependent on successful review of the annual progress report. ERS reserves the right to reduce the amount of funding if the amounts allocated in the previous year has not been fully spent or not used according to the ERS CRC guidance or to withdraw the "ERS CRC Badge" in case of non-compliance to the terms of the CRC agreement.

The CRC Chairs will receive a feedback letter by email around two (2) months after the submission of their annual progress report. The ERS CRC Guidance would continue to apply for the next CRC period, especially the clause 6.7 Reports and 6.12 Liability and the access to the benefits (e.g., section 6.9 Meeting facilities and 6.11 Promotion).

6.8 Regulatory and ethical issues

The institution of investigators from the CRC would need to endorse the legal sponsor responsibility of any clinical studies and trials conducted in the frame of the CRC. ERS will not endorse the legal sponsor responsibility for any clinical studies or trials.

The initiative should seek Ethics Committee approval on clinical studies/trials in at least one Ethical committee per country involved.

All projects involving clinical trials should comply with the relevant local and international specific regulations and as a requisite to be considered, provide proof of having the necessary insurances in place, as well as an EudraCT number in the case of drug-based research.

6.9 Meetings

The ERS CRC funding cannot be used to cover meeting expenses during or in relation to the ERS International Congress (travel, registration or accommodation), except for patient representatives as defined in the relevant ERS travel policy. If the CRC is approved, the ERS Office can offer meeting facilities (room with audio-visual equipment) at the ERS International Congress. Meeting room request form will be sent by the ERS Office to CRC Chairs in May each year.

If funds are used for meetings organised outside of the ERS International Congress through the ERS Office, then, the [ERS CRC and Task Force travel policy](#) for reimbursement will apply. Claims for reimbursement of expenses must be accompanied by the relevant receipts.

Meeting facilities also exist at the ERS Headquarters Office in Lausanne, Switzerland and at the ERS Office located in Brussels, Belgium with a limited number of 15 participants. In such case, the meeting facilities



are free of charge for the CRC, but Travel/Accommodation/Catering expenses will be charged on the ERS CRC funds.

For meetings organised at the ERS Office or to an external place, logistical support (travel/accommodation) can be provided upon request to ERS Office up to 3 months before the meeting.

6.10 Joint CRC with other organisations

Applicants are encouraged to seek for collaboration with other organisations. In such a case, it should be highlighted in the CRC proposal. If collaboration with another organisation is approved, a written agreement will need to be established by all parties outlining the major terms of collaboration in accordance with ERS policies. This will include details of how the expenses and outcomes of the project will be handled.

6.11 Promotion

The CRC can be promoted through ERS promotional channels, and a dedicated webpage can be set up on the ERS website. The initiative can use the ERS logo on its website and for its correspondence during the period for which it has been endorsed.

6.12 Liability

Each CRC, through its Chairs, has total responsibility related to all actions and activities undertaken using the ERS name and logo. These actions and activities should be in compliance with the CRC agreement. ERS should be informed in advance of any action or activity performed by the CRC (e.g. involving ERS name and logo) which is not part of the approved CRC agreement. Failure to inform ERS will result in immediate cessation of the CRC recognition and funding.

6.13 Intellectual property

Each CRC proposal should clearly define the sharing between all partners involved, the ownership or sharing of intellectual property or any other product or outcome from the work performed under the CRC. This should also include any subsequent financial revenue.

6.14 CRC assets sharing

The ERS CRC umbrella intends to establish a collaborative spirit and the ERS CRC programme encourages sharing of project assets between CRCs. Therefore, ERS expects CRC Chairs to assess thoroughly requests made through the ERS Office to share any results of the CRC (existing patient data, registries, biobanks or samples collected) within the frame of the CRC as well as protocols, SOPs or templates with other researchers to answer additional research questions or to support the setup of other projects.



7 Appendix 1 - CRC online application: Checklist of the requested fields/documents

This appendix represents a checklist of the different requested fields of the CRC online application form and /documents which would support you to prepare your CRC application and submit it to the ERS CRC application platform.

Only CRC applications received through the ERS CRC application platform will be considered for review. Any exceptional case must be discussed upfront with the ERS Office by contacting scientific@ersnet.org before the submission deadline of October 15th.

Description	Completed																												
CRC online application form (sections 1 to 3 describe the requested fields to be completed online)																													
1. CRC Description																													
1.1 Title	<input type="checkbox"/>																												
1.2 Lead Assembly and Groups relevant for your proposal: And Tracks: <input type="checkbox"/> Airway diseases <input type="checkbox"/> Interstitial lung diseases <input type="checkbox"/> Paediatric respiratory diseases <input type="checkbox"/> Pulmonary vascular diseases <input type="checkbox"/> Respiratory critical care <input type="checkbox"/> Respiratory infections Sleep and breathing disorders <input type="checkbox"/> Thoracic oncology	<input type="checkbox"/>																												
1.3 Scientific Summary (1'700 characters max)	<input type="checkbox"/>																												
1.4 Background and relevance	<input type="checkbox"/>																												
1.5 Objectives	<input type="checkbox"/>																												
1.6 Overlaps /Synergies with ongoing CRCs within the portfolio Indicate potential overlaps/synergies identified - if it exists some - with ongoing CRCs . We recommend prior discussion with CRC Director and ongoing CRC Chairs by contacting the ERS Office (scientific@ersnet.org) where you will be directed to the appropriate persons.	<input type="checkbox"/>																												
1.7 Timelines of Deliverables / Milestones We expect maximum two deliverables per year, where one is mandatory and pre-defined, and the other is optional and to be decided by applicants.	<input type="checkbox"/>																												
<table border="1"> <thead> <tr> <th>Year</th> <th>Deliverable / Milestone</th> <th>CRC Mandatory deliverable*</th> <th>to be defined by applicants</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Established Governance model *</td> <td>X</td> <td></td> </tr> <tr> <td>1</td> <td>CRC Project core deliverable 1_year1</td> <td></td> <td>X</td> </tr> <tr> <td>2</td> <td>Research agenda summarised in a published editorial/article*</td> <td>X</td> <td></td> </tr> <tr> <td>2</td> <td>CRC Project core deliverable 1_year2</td> <td></td> <td>X</td> </tr> <tr> <td>3</td> <td>Detailed project implementation plan including funding strategy and budget*</td> <td>X</td> <td></td> </tr> <tr> <td>3</td> <td>CRC Project core deliverable 1_year3</td> <td></td> <td>X</td> </tr> </tbody> </table>		Year	Deliverable / Milestone	CRC Mandatory deliverable*	to be defined by applicants	1	Established Governance model *	X		1	CRC Project core deliverable 1_year1		X	2	Research agenda summarised in a published editorial/article*	X		2	CRC Project core deliverable 1_year2		X	3	Detailed project implementation plan including funding strategy and budget*	X		3	CRC Project core deliverable 1_year3		X
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3	CRC Project core deliverable 1_year3		X																										
* Mandatory deliverables (see section 3. Application and approval process for more details).																													



<p>1.8 Proposed publications</p> <p>Indicate the proposed publications expected from the CRC.</p> <p>Note that any statement or other official communication in the name of the Society must be approved by ERS before publication.</p>	<input type="checkbox"/>
<p>1.9 Risks</p> <p>Indicate the top 3 risks linked to the core deliverables of the CRC foreseen along with the mitigation actions to monitor each risk.</p>	<input type="checkbox"/>
<p>1.10 Patient input factors</p> <p>If public and patient input is being considered, please explain the role you envisage for patient input, how you think this could add value to your CRC, and what form(s) of input would be appropriate/ desirable. Please outline your plans for patient input, including key activities and the ways in which patient perspectives will be incorporated into the other aspects of the CRC. We recommend contacting ELF in advance to discuss plans for involving patients and the support available: info@europeanlung.org</p>	<input type="checkbox"/>
<p>1.11 Lay Summary (3'000 characters max)</p> <p>Lay summary will be shared with patients; it should be written in such a way that a non-scientist can easily understand the project aims, outcomes and potential relevance to future practice. It should also include how the project plans to involve patients.</p> <p>Please refer to the ERS Webinar : How to write a lay summary and public dissemination</p>	<input type="checkbox"/>
2. Stakeholders	
<p>2.1 Proposed Chairs</p> <ul style="list-style-type: none"> - Chair 1 AND Chair 2: Name (first, last), Title, Institution, Department, mailing address, Post code and City, Country, Email address and Telephone number. 	<input type="checkbox"/>
<p>2.2 Members of the CRC</p> <ul style="list-style-type: none"> - Name, specialty, institution, city, country <p><i>[enter as many members as you have]</i></p> <p>The project membership should be <u>multicentric</u> and a <u>significant participation of European countries</u> is expected. Participation of institutions based outside of Europe can be included.</p> <p>We recommend considering an adequate project membership diversity. The presence of ERS early career researchers (< 40 years old), gender balance, Equity, Diversity and Inclusion (EDI) (see ERS Diversity and Inclusion policy).</p>	<input type="checkbox"/>
<p>2.3 ELF involvement <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If public and patient input is being considered, please explain the role you envisage for patient input, how you think this could add value to your CRC, and what form(s) of input would be appropriate/ desirable. Please outline your plans for patient input, including key activities and the ways in which patient perspectives will be incorporated into the other aspects of the CRC. In case you do not see a role for patient involvement, at the review stage, ELF may suggest how patient involvement could benefit the CRC and propose ways of involving patients.</p>	<input type="checkbox"/>
<p>2.4 Other Parties <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<input type="checkbox"/>
<p>If yes, if the proposal is for a joint CRC with (an)other society-ies, please indicate:</p> <ul style="list-style-type: none"> - Name(s) of the Society-ies and: Nature of the contributions (i.e.. Financial, support) 	<input type="checkbox"/>



<i>[enter as many Societies as you have identified]</i>	
<p>If yes, if industry partnership is foreseen, please indicate:</p> <ul style="list-style-type: none"> - Name(s) of the industrial company-ies and: Nature of partnership (i.e.. Financial, support) <p><i>[enter as many industrial companies as you have identified]</i></p>	<input type="checkbox"/>
3. Budget Details	
<p>3.1 Expenditure details</p> <p>Source (i.e. Meetings, salaries, events, etc) / Amount (€) / comments</p> <p><i>[enter as many sources as you have identified to spend budget]</i></p> <p>After approval, ERS will support the CRC for the three years duration period allocating a total budget of 45,000.00 Euros. Please provide a detail of the sources of expenditure which will be covered by the CRC funds.</p> <p>Salary expenditure is anticipated for administrative staff, NOT for the salary of expert stakeholders involved in the project</p>	<input type="checkbox"/>
<p>90' Elevator Pitch video</p> <p>Please note that you need to upload a 90-second elevator pitch video explaining the main objectives, how they will be achieved and how they will benefit the respiratory community and patients. We suggest creating a MP4 video in PowerPoint. Instructions on how to create such a video can be found here.</p> <p>To upload this video, please contact scientific@ersnet.org and we will provide you with detailed information on how to proceed.</p>	<input type="checkbox"/>
Chair 1_ One page CV with his/her 5 main relevant publications	<input type="checkbox"/>
Chair 2_ One page CV with his/her 5 main relevant publications	<input type="checkbox"/>
Chair 1_ Declaration of Interest (DoI)	(*)
Chair 2_ Declaration of Interest (DoI)	(*)

*The Declaration of Interest (DoI) of both Chairs will be requested by the ERS Office through the myERS platform after the submission deadline. Both Chairs should ensure to reply back to the ERS Office in order to have the application fully completed.