

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



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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 section 6. *Rules for CRCs*.

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. Typical outputs of an ERS CRC include scientific products, such as original articles published in scientific journals or abstracts submitted for presentation at scientific congresses.

For CRCs to ultimately become self-sustaining, it is expected to develop a long-term strategy to secure inward investment. This strategy may involve approaching relevant grant funders at a local country level, Industry Partners, or seeking European Commission funding. However, ERS recognises that securing inward investment may not be feasible for certain CRCs, depending on their specific 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, novel 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 considered.
- Optimise patient access to, and support for, the resulting outputs of the CRC.

The European Lung Foundation (ELF; <https://europeanlung.org/en/>) 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 **prioritize research questions** that address unmet medical needs and focus on the use of real-world data in multicentric studies. Based on these questions, the CRC should develop and share new research protocols on clinically orientated topics and lead the development of priority research projects in the relevant field of interest.

Each year, the ERS Science Council identifies key research areas representing gaps in the ERS CRC portfolio and encourages proposals in these fields by publishing '**highlight notices**'. These highlight notices are developed after consultation with all ERS Assemblies, aligned (where possible) with future funding calls from the European Commission and ratified by the Science Council. The highlight notice(s) is advertised on the [CRC website](#) once it is approved by the Science Council and the Executive Committee.

The ERS CRC programme encourages proposals which could **foster synergies between the CRCs**. It is highly recommended to have an upfront discussion with the existing CRC Chairs and the CRC Director before preparing an application 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 should 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 ERS Assembly(ies).

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:

- 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.

(For the complete description of the requested fields, please refer to *Appendix 1 - CRC online application: Checklist of the requested fields/documents*).

1. One page CV with the 5 main relevant publications of both Chairs is provided, justifying their expertise in the field and their role/responsibility in the CRC proposal.
2. The annual Declaration of Interest (DoI) is 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 has been submitted. We suggest creating an 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 with significant participation from European countries. Institutions based outside of Europe may also be included.
- It focuses on disease areas of respiratory medicine or related issues.
- The objectives and ambitions of the proposal are to develop a comprehensive work programme that is not limited to a single clinical study or trial.
- At least one of the Chairs is an ERS member.

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

The 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 (WG), to comment on the content of the application. The CRC Director (and/or Director elect, if applicable) will review all applications received.
3. All reviewers are required to notify the ERS Office (in writing *via* e-mail) of any 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 found to have a direct Conflict of Interest, the ERS Office will seek an alternative reviewer.

4. The reviewers will evaluate the eligible CRC proposals against the following criteria:
 - **Scientific excellence** (30%): Assess the quality, significance, and originality of the proposed scientific work, as well as analyse the specific contribution and impact that the CRC will bring to the respiratory community.
 - **Feasibility** (30%): Evaluate the likelihood that the core deliverables of the CRC can be achieved within the stated timelines. This includes plans for obtaining sustainable external funding and rationale for the requested ERS funding.
 - **Program Management plan** (20%): Evaluate the competence of the leadership, the project membership diversity, management, and governance arrangements for implementing the CRC proposal.
 - **Risk mitigation** (10%): Rate the identification of clearly stated risks and their corresponding mitigation strategies linked to the core deliverables of the CRC.
 - **Patient involvement** (10%): Assess the involvement of patients and the relevance of ELF engagement in the proposal outline/planned prospective engagement if the CRC is awarded.
5. ELF will also review the applications to rate 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 reviewing 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 other applications. These proposals will not be favoured during the reviewing process but for applications evaluated of equal excellence (i.e. equivalent scores and votes), topics including highlight notice(s) would be prioritized.
7. Based on the reviewers' assessment and taking into consideration the reviewing scores, the CRC Director will validate the list of applications to be proposed for discussion with the CRC WG; and threshold for being awardable will be set according to 1) the overall quality of the applications received and 2) the budget allocated to the programme by ERS.
8. Scores of all proposals will be presented at the CRC WG meeting alongside a summary of the awardable CRC proposals by the CRC Director and with input from the allocated 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 WG will be reminded of their duty of confidentiality during this meeting.
9. The CRC WG will then vote on the proposals to be selected and funded.
10. The ERS Science Council will decide based on the recommendation of the CRC Director on approval or rejection of the CRC applications. Scientific and operational changes may be requested from the awarded CRCs as appropriate. The ERS Science Council may also make recommendations on CRC membership.
11. The ERS Science Council decision will have to be finally endorsed by the ERS Executive Committee.

The process from the reviewing and approval procedure takes around four (4) months (until February of the following year) until final decision. The applicants of successful and unsuccessful CRC proposals will receive notification by email.



4 Project Development

For all approved CRC proposals, a kick-off teleconference will be organised between the CRC Chairs, the CRC Director, a nominated CRC Link person (section 6.4. *CRC Link person*) and a member of the ERS Office to describe the terms and conditions of the programme, discuss operational aspects, benefits, and, eventually, funding and supplementary background information 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, as representative of the CRC members, will be asked to sign a CRC agreement to settle the terms of collaborations between ERS and the CRC.

Annual reporting is expected in order for the CRC Director and CRC WG to assess project advances against the CRC application and to review the *per annum* budget spent (section 6.7 *Reports*). Any substantive changes in the objectives, deliverables, strategy or budget of the CRC must be reported to the ERS Office immediately and could require approval by the ERS Science Council.

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

5 Dissemination and communication

ERS advises selecting a unique CRC name/acronym that differentiates it from existing CRCs. It is recommended to ensure that the name is easy to pronounce, and flexible enough to accommodate the future growth and expansion of the CRC. A well-chosen name can enhance your CRC's visibility and identity, contributing to its success.

Preliminary CRC results may prompt abstract submissions to scientific congresses, especially ERS Congress. When submitting to ERS Congress, highlight the CRC connection by including the CRC name or stating "an ERS Clinical Research Collaboration" in the title or core text. This will help the ERS office identify your abstract and promote it through dedicated communications around ERS congress.

Results of CRCs should lead to 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 standard review and assessment procedures.

ERS encourages CRC networks to produce content for the [ERS Respiratory Channel](#) (e.g., Coffee Talk) to aid disseminating the results of the CRC. In case of interest, the ERS Office should be contacted for further details.

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*.

If during or after the CRC research project, the CRC Steering Committee considers the development of Clinical Practice 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.



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 WG, 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 project membership diversity should be considered, with a strong emphasis on including ERS early career researchers (< 40 years old), striving for gender balance, promoting Equity, Diversity and Inclusion (EDI) (see [ERS Diversity and Inclusion policy](#)), and including patient representatives.

The CRC network 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 revising (where relevant) the CRC Chairs/core Leadership to promote emerging leaders and include new perspective to the CRC. 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 fund is not to be considered as an ERS grant; it is funding that ERS has earmarked for up to three (3) years for expenses during project development and conduct. The approved CRCs will be allocated 15,000 Euros (€) per year by ERS for a maximum of three (3) years, for 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 CRC project accounts must be approved by the ERS Office in advance. For the use of the ERS CRC fund regarding meeting expenses, refer to section 6.9 Meetings.

The release of the *per annum* ERS CRC fund is dependent on successful review of the annual progress report (section 6.7 Reports). The allocated ERS CRC fund 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 is unable to provide financial support for the research or clinical trials that the network intends to conduct. If appropriate and relevant, it is recommended to submit grant applications for research and/or network funding to the EU and/or other funding agencies with the aim to secure funding for the CRC activities.

ERS provides independent funding to ELF to support patient involvement at a basic level. However, for patient participation in CRC meetings, funding must be provided by the ERS CRC fund, 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.

The ERS CRC fund could be used for the creation of a unique CRC specific logo and website. If interested, the ERS Marketing & Communication team can assist with logo development, and ELF could set up and host the CRC website, provided there is sufficient budget and staff capacity. Any such interest should be submitted to the ERS office and ELF respectively for evaluation and approval before proceeding.

6.4 CRC Link person

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

1. Provide close support to the CRC 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 WG 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 members.

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

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 apply. The level of engagement is mainly related to additional fund-raising activities and involvement of the ERS Research Agency (ERS RA).

Industry partnerships with CRCs are encouraged where considered appropriate and beneficial for the delivery of the objectives of the CRC.

Engagement with potential industry partners aims to build collaborative partnership benefiting both parties. Collaboration with the CRC Chairs is required to identify potential interested Industry Partners. Potential partnerships must be discussed with the CRC Director and the ERS Office to ensure adequate coordination and minimise overlapping of activities. The CRC chairs retain project ownership, while the ERS RA facilitates bringing industries together, presenting projects, and soliciting interest, with CRC Chairs promoting their projects.

The ERS RA manages contract negotiations and ensures alignment of interests when engaging with industry partners, acting as a **neutral broker** between industry and academic researchers. This guarantees transparency in fund usage, industry inclusion within the CRC, agreement on benefits, adherence to timelines and deliverables, and proper oversight through project reporting.

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 for the setup 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 RA.
CRC fund	The CRC fund 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 operational staff, NOT for investigators involved in the project. 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 RA (i.e. pharmaceutical and medical device companies, other medical or research societies, foundations...), the CRC Chairs cannot claim to be an ERS RA 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 RA substantial funding needed to deliver and achieve major objectives of the CRC.
CRC fund	The CRC fund 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 CRC Tier Model. 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 research objectives, benefits offered to funding partners, a



	<p>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 CRC Director and the ERS Science Council Chair.</p> <ul style="list-style-type: none"> 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 relationship 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 RA 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 RA 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. Meetings can be organized through the ERS Office on request (<i>see section 6.9 Meetings</i>). 6. 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 fund 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 fund	The CRC fund 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%) of the funds received from funding partners to cover the costs of its neutral broker role as described in section 6.5 CRC Tier Model. 2. ERS, through the ERS RA, could have a broader role in the CRC, primarily in project management, to ensure that sub-projects activities are completed - outside of overall contract requirements with fund providers. This should be covered by the additional external funds received from funding partners. 3. The CRC Chairs must comply with the conditions of the collaboration agreement with the funding partners, including milestones, project objectives, access to data, and reporting terms. 4. The CRC Chairs determine the allocation of the additional external funds. Involvement of external consultants must be approved by ERS and should be restricted to tasks beyond the capabilities of CRC Chairs, CRC members, ERS early career members, ERS Office or academic institutions. External consultant engagement should be minimised and backed by compelling justifications. 5. The external funds from funding partners CANNOT be used to pay the salaries of investigators or CRC Chairs and patient representatives for their involvement in the project. However, the funds could be used to cover the costs of operational staff (e.g. Ph.D students, biostatisticians, data scientists, study nurse...) involved in the delivery of the CRC tasks defined in the budget. 6. The additional external funds from funding partners CANNOT be used for the development of Guidelines, Statements, or Technical Standards. 7. The ERS RA will set up the appropriate separate contracts with the participating academic institutions/partners to contribute to the expenses related i to the CRC tasks defined in the budget plan. ERS is a non-profit organisation and recommends that each participating institution either refrain from <u>applying overheads</u> or <u>limit them</u> to a maximum rate of 20%. 8. Any change from the original plans, - especially those related to the milestones and deliverables, the budget and its allocation, as well as the benefits for funding partners, must 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.

6.6 Duration of support

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

- **Initial ERS CRC funding support:** The approved 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 a 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, it is eligible to request for an additional year WITH ERS CRC funding (i.e. 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. **mid-March** (see clause 6.7 Reports). The request for 1-extra year of funding is not competitive but is subject to the following criteria:

- The outcome of the annual progress report review 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.

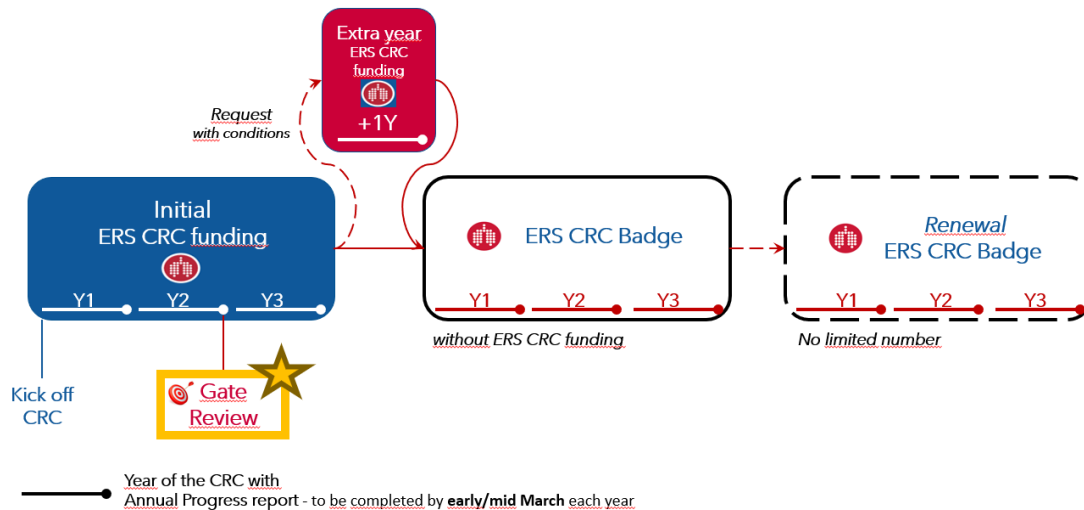
In case any of the above-mentioned criteria is not met, 1-extra year WITHOUT ERS CRC funding support could be granted allowing access to the benefits linked to CRCs (e.g., section 6.9 Meeting facilities and 6.11 Promotion) for an additional year.

- **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 "ERS CRC Badge" application is managed through the annual progress report process at the end of the ERS CRC funding period i.e. **mid-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. Requests for exceptions should 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", 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 annual progress reports, 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. These reports have to be sent to the ERS Office (scientific@ersnet.org) usually **mid-March each year**. The reports of the CRCs that are in their 3rd year will include requests for "1-extra year of ERS CRC funding" and for "ERS CRC Badge".

- The CRCs that are completing their second year of ERS CRC funding must address the status of 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 a funding strategy and budget.

! Gate review at Year 2: The CRC WG members will assess the progress of the CRC against the first two mandatory deliverables. If these deliverables have not been met, discussions about the termination or continuation of the CRC will take place during the review meeting.

After the first "ERS CRC Badge" period, this badge can be renewed. The annual report will need to include new plans including objectives and deliverables that will then be used to measure the CRC success.

To retain the "ERS CRC Badge", CRCs are expected to produce at least two publications (no editorial or review) during this period OR one publication in a journal with an Impact Factor > 10. This criterion is not exclusive, however, if it is not met, the reasons must be provided to the CRC WG for evaluation.

Failure to provide annual progress reports may result in the termination of the CRC and the removal of all benefits linked to CRCs. If applicable, any left-over of the CRC funds will be retrieved back to ERS.

Report assessment process will run as follows:

- The annual progress report, including the requests for "1-extra year of ERS CRC funding" and "ERS CRC Badge", will be forwarded to the CRC Link person, the CRC Director (and CRC Director-elect if applicable) and ELF for assessment and comments.



- Based on the reviewers' assessment, the CRC Director will validate the list of CRCs to be discussed at the CRC WG meeting.
- The CRC WG will discuss and provide recommendations on the following cases:
 - CRCs for which reviewers have raised concerns
 - Request for a "1-extra year of ERS CRC funding
 - Request for the "ERS CRC badge"
 - CRCs completing their 2nd year of funding (Gate Review at Year 2)
- The CRC WG will then vote on recommendations regarding termination of a CRC and approval or rejection of requests.

The progress status of all running CRCs and the recommendations made by the CRC WG 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" is contingent upon a successful review of the annual progress report. ERS reserves the right to reduce the amount if the funds allocated in the previous year were not fully spent or not used in accordance with the ERS CRC Guidance, or to withdraw the "ERS CRC Badge" in case of non-compliance with the CRC agreement terms.

The CRC Chairs will receive a feedback letter by email approximately two (2) months after submission of their annual progress report. The ERS CRC Guidance will continue to apply for the next CRC period, particularly the clauses *6.7 Reports* and *6.12 Liability*, and 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 fund cannot be used to cover meeting expenses during or in relation to the ERS Congress (travel, registration or accommodation), except for patient representatives as defined in the relevant ERS travel policy. The ERS Office can offer meeting facilities (room with audio-visual equipment) at the ERS Congress. Meeting room request form will be sent by the ERS Office to CRC Chairs in May each year.

If meetings are organised outside of the ERS 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 fund.

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 will be featured on the ERS website and incorporated into the CRC portfolio alongside other ongoing CRC projects. Additionally, the ERS Office will create a dedicated webpage for the CRC, offering comprehensive details about the project, including its objectives and any associated website links. This webpage will be published on the ERS website for easy access.

During the endorsed period, the CRC should acknowledge ERS for its financial contribution. However, the use of the ERS logo in any correspondence, materials, presentations, communications and on the CRC's website requires prior approval from the ERS Office (see section 6.12 *Liability*).

Any publications resulting from the CRC during the endorsed period should include a statement acknowledging ERS for its financial contributions. This can be stated as follows: 'The [CRC name] ERS Clinical Research Collaboration acknowledges the financial support provided by the European Respiratory Society (ERS).'

The results of the CRC, key scientific publications and important CRC milestones can be shared through ERS dissemination channels like the ERS Newsletter, ERS Respiratory Channel and ERS social networks. Requests have to be submitted to the ERS Office for evaluation and processing.

6.12 Liability

Each CRC, through its Chairs, holds full responsibility for all actions and activities involving the use of the ERS name and ERS logo. These must be in compliance with the CRC agreement. Any action or activities not covered by the approved CRC agreement ERS, especially those involving the ERS name and logo, must be communicated and/or approved by the ERS Office in advance. Non-compliance, including failure to inform ERS, could lead to immediate termination 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 Disease domains and methods relevant for your proposal: Disease: <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 <input type="checkbox"/> Sleep and breathing disorders <input type="checkbox"/> Thoracic oncology Methods: <input type="checkbox"/> Cell and molecular biology <input type="checkbox"/> Endoscopy and interventional pulmonology <input type="checkbox"/> Epidemiology <input type="checkbox"/> General respiratory patient care <input type="checkbox"/> Imaging <input type="checkbox"/> Physiology <input type="checkbox"/> Public health <input type="checkbox"/> Pulmonary function testing <input type="checkbox"/> Respiratory intensive care <input type="checkbox"/> Surgery <input type="checkbox"/> Transplantation	<input type="checkbox"/>																												
1.3 Scientific Summary	<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 ERS CRC portfolio Indicate potential overlaps/synergies identified, if any, 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. <table border="1" style="width: 100%; margin-top: 10px;"> <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_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_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_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_year1		X	2	Research agenda summarised in a published editorial/article*	X		2	CRC Project core deliverable_year2		X	3	Detailed project implementation plan including funding strategy and budget*	X		3	CRC Project core deliverable_year3		X	<input type="checkbox"/>
Year	Deliverable / Milestone	CRC Mandatory deliverable*	to be defined by applicants																										
1	Established Governance model *	X																											
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2	CRC Project core deliverable_year2		X																										
3	Detailed project implementation plan including funding strategy and budget*	X																											
3	CRC Project core deliverable_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 and public involvement</p> <p>If considering Patient and public involvement in your CRC, please describe their envisioned role, how their input could add value to your CRC, and the forms of input you find appropriate or desirable. Outline the plans on how to integrate their perspectives into the CRC. In case you do not see a role for such involvement, ELF may suggest potential benefits and propose ways to include patients during the review stage. However, we recommend contacting ELF in advance at info@europeanlung.org for discussing plans and available support.</p> <p>Please refer to the Virtual School on Patient and public involvement in research.</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>The project membership <u>diversity</u> should be considered with a strong emphasis on including ERS early career researchers (< 40 years old), striving for gender balance, and promoting Equity, Diversity and Inclusion (EDI) (see ERS Diversity and Inclusion policy)..</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) <p><i>[enter as many Societies as you have identified]</i></p>	<input type="checkbox"/>



<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"/>
<p>3. Budget Details</p>	
<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 could be anticipated for operational staff, NOT for the investigators and CRC Chairs involved in the project.</p>	<input type="checkbox"/>
<p>90" Elevator Pitch</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 in advance and we will provide you with detailed information on how to proceed.</p>	<input type="checkbox"/>
<p>Chair 1_ One page CV with his/her 5 main relevant publications</p>	<input type="checkbox"/>
<p>Chair 2_ One page CV with his/her 5 main relevant publications</p>	<input type="checkbox"/>
<p>Chair 1_ Declaration of Interest (DoI)</p>	<p>(*)</p>
<p>Chair 2_ Declaration of Interest (DoI)</p>	<p>(*)</p>

*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 to the ERS Office in order to have the application fully completed.