

Joint call for International Clinical Trial on Rare Cancer Drug Development



ATTRACT

Accelerate Together Rare Cancer Treatment



Fondation
pour la recherche
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contra el cáncer



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Foundation for Clinical
Cancer Research

Guidelines on Patient Centricity and Patient Involvement

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These guidelines form the instructions on how to write a project proposal for the patient advocacy committee (PAC). The guidelines are focused on patient centricity and patient involvement. Patient centricity signifies the focus of the project being on the need and wishes of patients, whereas patient involvement indicates the active involvement of patients and/or patient organisations in the trial design, the conduct of the research, and the communication of the results to the patient community. Where the preproposal phase might be too early to follow all of these instructions, it is expected that during the full-proposal phase attention is paid to all of them.

We adopt the definition of patient partner provided by Patient-Centered Outcomes Research Institute (PCORI). PCORI's definition of patient partners includes patients (those with lived experience), family members, caregivers, and the organizations that are representative of the population of interest in a particular study.

PATIENT INVOLVEMENT

The submission of a Patient Involvement Plan as part of the pre-proposal application is required. The plan should describe patient partner involvement processes during the generation of the project application as well as during the implementation of your project. It describes involvement, such as how you engage with the patient community when your research question is defined, while the proposal is written, when it is being submitted and resubmitted.

APPLICATION FORM

Be objective and honest in your application. Ensure that your application for the patient advocacy committee (PAC) is in accordance with your application for the scientific expert committee (SEC).

Bear in mind that the PAC will only review the "PAC evaluation section".

Be aware that your application for the PAC must be in layman's language and make sure that used jargon is explained. Use clear argumentation with a logical structure.

Make use of clear figures and diagrams to support your text.

Your applications for the PAC will be read and judged by patients, therefore we advise you to involve one or more patients/patient organisations in proofreading your application before applying. Actively ask them for suggestions regarding content and language.

PATIENT CENTRICITY

Pay sufficient attention to explaining the need of your research and the added value for patients. Address the question 'Did the demand for this research come directly from the patients of the target group?'. If so, explain the conversation you had with these patients.

If the application is a follow-up of the results from (a) previous study/studies, please elaborate on the status and the results of this previous study. Explain in which way the previously gathered results will add value to the current proposal.

Explain the choice for the used inclusion criteria for study participants.

Elaborate on the expected process after the project. Think about questions like: Will there be a need for a follow-up study? Will the treatment be practically feasible? Will the treatment be available for a wide spectrum of patients? Is contact already made with other centres? Etc.

Explain the possible burden and benefits that patients can experience by participating in the study. Keep in mind that effects in quality of life are equally as important as effects in life expectancy. Pay attention to the follow-up of both physical and mental side-effects during the study.

Explain the cost-benefit ratio for participants. Do the expected results outweigh the burden and risks? Did you consult patients in the evaluation of the cost-benefit ratio?

Clearly explain the interventions and steps that participants will undergo in the process and make sure the burden for participants is minimised as much as possible.

Explain the communication and dissemination plan of the results among the patients.