

CLINICAL ACADEMIC CENTRES EXTERNAL EVALUATION AND FUNDING 2022

GENERAL ORIENTATIONS FOR THE CAC

AICIB, based on the panel evaluation recommendations, prepared this document that aggregates general orientations for the CAC development.

CAC in preparing the implementation plans based on the individual evaluation reports, should also consider these global orientations.

1. GOVERNANCE STRUCTURE

Create a clear governance structure, including:

- A CAC leadership that is empowered to be responsible for the CAC organization.
- A management and an organisational structure with clear governance rules for the collaborative interactions amongst the different partners under the CAC umbrella.

All the entities involved in the CAC should be aligned and committed, work together for a shared common strategic goal and use a joint approach to find solutions to the challenges. CAC brings education, entrepreneurship, research and health care together in an integrated way. CAC members should be integrated and have a clear vision of further development and a strategy of how each one of the CAC members can contribute to the CAC as a whole. All should be involved in the planning or strategic objectives of the CAC. The responsible person for each of the CAC members must be represented at the highest level in board decisions. The three CAC DNA-strings must be integrated within one body through the development of collaborative activities on patient care, research, and education (training).

2. STRATEGY

- Develop a realistic and sustainable strategy of the JOINED activities with clear prioritisation of a limited number of relevant health problems.

Choose, define the **areas /subjects** that are priorities, in which the CAC is excellent, that are patient-oriented and correspond to the population needs. This creates critical mass, so that the CAC can be a competitive centre at an international level, capable of delivering relevant results and being selected for participation in relevant industry-sponsored trials. The alignment of strategic planning and policy making on an international level (global themes), national level (agenda-setting), sectorial level (e.g., university medical centres) and fostering the translation of scientific results to clinical practice and to the productive sector should be promoted.

3. LEGAL ENTITY

- Create for each CAC a structure of an **association** with recognition, a fiscal entity, and an own bank account.

A structure of an association is clearly needed with generation of a money flow for combined responsibilities and activities. The consortium is an appropriate structure to link the entities, but the CAC needs an association to become a legal entity, and to have the capacity to sign agreements, manage accounts and get funds for the CAC (managing funds from projects and trials in the name of the entities involved in the consortium is a good way to reach financial autonomy). The contracts (eg. human resources, clinical trials, competitive grants) should be made by the CAC. The CAC legal structure has to be such that the European Union can directly sponsor innovative projects of the CAC and the CAC can apply for funding directly to the EU.

4. HUMAN RESOURCES

The human resources and researchers should feel part of the CAC. It is crucial to create a human resources strategy plan, which approaches themes like:

- Implementation of protected research time for MDs that are CAC members with appropriate evaluation.
- Implementation of formal MD-PhD programs to increase the number of clinician-scientists.
- Valorisation of research for career progression.
- Internal research training program, including pre- and post-graduate training.

Relatively to researchers give guidance for:

- Publish with their CAC affiliation (besides the faculty and/or the hospital);
- Register on ORCID.

5. FUNDING

CAC must raise funds. The funding can come from:

- Structural financial donations from partners. The partners can show commitment through financial investments in the CAC in an accountable way (in this case, agree upon the budget proposals before granting).
 - Clinical trials.
 - Competitive national and international funding.
 - Licenses/patents.
 - Others.

6. BUDGET

The CAC should spend the money on:

- Shared/common infrastructure for research (biobanks, trial centres, data, statistical aid, research hardware).
- Common structures for initiation of investigator-initiated studies and for clinical trials.

- A lean clinical trial unit with sustainable funding and a healthy mixture of investigator initiated and industry-sponsored trials.
- A coordinating team for research and training for coordination between university and healthcare system, trying to increase capacity for the healthcare researchers, increase academic research and interaction between basic and clinical groups. Also to manage common structures and to promote common research, planning, cooperation, and common support.
- A transversal support team for support of clinical research not ascribed to specific lines or groups but to support every group, that should include study coordinators, methodological, statistics and funded research grants support.
- Fellowships for researchers, in particular MDs, and to equip them with flexible usable funds so that they can pursue competitive research projects (in the case of CAC with economic independence).

7. FINANCIAL SUSTAINABILITY

The CAC should make a financial sustainability plan, including rules for safeguarding income to the CAC from clinical trials, licenses, and structural financial donations from partners. CAC should be completely autonomous and reach economic independence. To have this the CAC has to create an association, define clear rules, spend the money on infrastructure for research, have critical mass, generate income and let the CAC make manage research. The partners (eg: hospital or faculty) should be paid if they have expenses arising from the CAC. The economic autonomy and independence should be built and demonstrated, including a specific budget and accountability, incomes and costs, memorandums, capacity to agree and operate.

8. REPORTS

Prepare an annual activity plan including a timeline, with continuous analysis, monitoring and evaluation system.

Prepare a common memorandum of the annual CAC activities including a scientific and an economic report. The economic report should mention incomes and expenses by type. The scientific report should include at least:

- Structures/Human resources/Researchers and research groups that belong to the CAC, their affiliation and activity/Scientific areas/Projects/Clinical studies/Clinical trials/Publications/ Patents/ Innovation.
- European activities and funding.
- Indicators (such as the ones indicated in Appendix I).

9. COLLABORATIONS

Establish national and international collaborations. Membership of international partner organisations both clinical, as well as fundamental research, is very important.

10. CAC'S VISIBILITY AND COMMUNICATION

Create a CAC logo. Create a webpage for the CAC, publish the activities and news from the CAC. Improve the CAC's visibility and communication inside and outside the CAC members. Put the CAC branding in all of the partners entities, including departmental signs, posters or publications, websites. Publish with the CAC affiliation.

APPENDIX I – CAC INDICATORS (EXAMPLES) (per year)

- N.º human resources (per entity and per sex)
- N.º MD-PhD
- N.º PhD
- N.º MDs with protected time
- N.º researchers (per sex)
- N.º researchers with ERC
- N.º international workers and students
- N.º research projects
- N.º clinical trials (researcher initiated), per phase of drug development
- N.º clinical trials (industry sponsored), per phase of drug development
- Cumulative Impact Factor (JCR) of publications
- N.º JCR indexed publications (classified by ARLE –Article, review, letter, editorial, meeting abstracts, other)
- % publications in 1st quartile
- % publications with international collaboration
- N.º publications on open access
- N.º of Clinical Practice Guidelines
- N.º citations
- N.º active international funded research projects
- N.º active international funded research projects that the CAC lead
- Success rate of applications to competitive funding
- Incomes in the period
- % Funding from public sources
- % Funding from international sources
- EBITDA
- N.º patents
- N.º national partnerships

N.º international partnerships and networks

CT: Internal processing time of the processes, from the submission of the study by the Promoter to the signing of the respective contract by the health unit

CT: Recruitment time of the first patient

CT: Patient recruitment rate