SIRIC PROGRAMME 2018-2022- MID-TERM REPORT (2020)
EVALUATION FORM

Project number	SIRICeval20-011
Name of the SIRIC	CARPEM
Name of the SIRIC Director	LAURENT-PUIG Pierre
Name of the Reviewer	2

Reviewer 2 has largely focused his/her comments/scores on the Social Science elements of the programme.

General information

The SIRIC designation aims to offer new opportunities for conducting translational cancer research, thus helps optimising, accelerating and disseminating the production of new knowledge and its application to cancer care. The SIRIC programme should increase the link between the different dimensions of research (basic, clinical, public health, epidemiology, and human and social sciences), by concentrating a critical mass of experts (physicians, researchers, engineers, healthcare workers and patients).
The role of a SIRIC is to make big improvements in the quality of research organisation, knowledge production, transfer of innovation into practice and care organisation, and new outcomes dissemination to all potential beneficiaries.

The SIRIC programme is a French National Cancer Institute's policy in research structuring initiated in 2011. The importance and priority of this flagship programme have been reinforced in the 2014-2019 Cancer Control Plan with a second call for designation, launched in 2017.
This second (2017) call for designation was open to previously designated sites and to new applicants. It has resulted in the designation of 2 new SIRICs (CURAMUS and ILIAD) and the renewal of 6 SIRICs (BRIO, CARPEM, CURIE, LYriCAN, MONTPELLIER and SOCRATE 2.0) for a 5-year designation period (2018-2022). It is addressing specific challenges related to anticipated needs, in order to fight cancer more effectively.
The current mid-term evaluation aims at obtaining a first scientific assessment of the progresses and achievements made by the 8 SIRICs during the 1st period (from January 2018 to June 2020) in order to make recommendations to them on scientific objectives and/or strategies for the 2nd period (July 2020-December 2022).

The mid-term report will be evaluated using 13 criteria (see below).

Each criterion should be scored from 0 to 5 as follows:
0: null ; 1: very weak ; 2: weak ; 3: good; 4: very good; 5: excellent.

1. SIRIC governance and management structure with executive and scientific committees

- Adequacy of the governance organisation for the scientific, administrative and financial management of the SIRIC
- Director of the SIRIC: appropriateness of his/her commitment for the SIRIC organisation, administrative and financial management
- SIRIC managerial and scientific committees: adequacy, role and responsibility of the members
- Respect of the gender equality within the governance
- Commitment of the partner institutions in the SIRIC organization and shared resources
- Adequacy of the scientific management of the SIRIC: progress of the integrated research programmes, inter-programme exchanges, national and international collaborations, dissemination activities
- Appropriateness of the SIRIC administrative services: oversight of shared resources, budget management and accounting processes

Comments on criterion 1:

(Please feel free to use as much space as needed)

A robust structure is in place to support strategic decision making and operational management. The first SiRIC was created in 2012 and experienced a delayed start establishing CARPEM due to delays in setting up funding. The first two years involved restructuring/merging aspects of the SIRIC and establishing a consortium agreement across the respective institutions (Hospital/Uni/Inserm). The respective groups meet at regular intervals and feedback is acted upon by the work packages. The Scientific Advisory Board was partly renewed for this SiRIC involving 9 international leading experts. Achievements and scientific plans have been assessed by the SAB. The IRP3 ethical/social programme was acknowledged as innovative, forward thinking and important. Is there representation from social sciences on the SAB? There is gender balance in the programme management team. The Steering Committee includes patient representation, representation across the 3 IRPs, participating research teams and centres, and technical representative. The Committee defines scientific strategy, financial management, and operational issues. In addition, there is a CARPEM Council consisting of leaders of clinical teams, research teams, platforms. The Council make recommendations regarding points brought for discussion regarding budget, changes in structures, personnel, new teams, changes in scientific strategy.

A welcome element of the management/governance structure is the Advisory Translational Ethics Board (ATEB) which gathers patients, patient reps, and professionals together with ethicists. The ATEB oversees ethical and cultural dimensions of all CARPEM projects. The ATEB role is to advise the steering committee to improve projects in terms of ethics, information, returning results to patients.

CARPEM supports existing platforms from organizational and financial point of view rather than establishing new systems.

The CARPEM programme embeds patient experience and debate in its governance. Patients and their representatives engage in constructing an appropriate normative/ethical framework.

Specific recommendations for the 2nd period of the SIRIC designation:

(Please feel free to use as much space as needed)

2. Establishment of shared resource facilities to support the SIRIC integrated research programmes

- Development or creation of efficient and operational transversal platforms (genomics, imaging, animal models, etc)
- Development or creation of shared facilities and joint services (methodology, biostatistics, bioinformatics, regulatory and ethical procedures, etc)
- Establishment or development of high-quality biobanks with linkage to clinical and follow-up data and subsequent sharing
- Contribution of the transversal platforms and shared facilities and services in the integrated research programmes

Comments on criterion 2:

(Please feel free to use as much space as needed)

A number of databases and teams with specific expertise support the IRPs.

CARPEM currently supports 4 platforms, animal housing facilities and biobank dedicated to clinical diagnosis and research. CARPEM Management Team has implemented a new consent form for all cancer patients in the three hospitals. This was developed in consultation with CARPEM Patients Committee. Allows for conservation of samples for future research.

Several databases are used by CARPEM researchers including: REDCap data collection tools (used across the world); integrating open and private datasets - CARPEM researchers developed an approach to link public and private datasets using geographical data –able to look at environmental and social determinants of cancer. Geocancer was launched in 2018 with ambition of integrating environmental data with patient cancer data. Covid 19 – GeoCancer system was adapted and transformed into GeoCOV to integrate COVID patient data with spatial information.

Teams with specific expertise:
Medical Ethics – ETREs (EThics, REsearch, translations) includes ethicists, sociologists, anthropologists, philosophers, lawyers and physicians linking Medicine to Human/Social sciences. Their 3 main areas of work with CARPEM:

- Help CARPEM teams maintain patient-centred approach and to identify and address ethical issues within the current legal framework in research and care pathway
- Develop specific research program dedicated to ethical issues that may emerge with new practices in personalised medicine
- Facilitate greater patient involvement and engagement in CARPEM projects in patient centred and personalised medicine

Members of this team develops empirical research making connection between patients, patients reps and society on one hand and health profs on the other.

CEPEC – early clinical trials centre – Do early trials include QoL/PROM assessments? Scope for further collaboration with social/human sciences?

Specific recommendations for the 2nd period of the SIRIC designation:

(Please feel free to use as much space as needed)

Consider the role of the Medical Ethics team in the work plans of each IRP (especially 1 and 2) going forward
Consider scope for including patient reported data in early clinical trials where appropriate with involvement of IRP3 and Medical Ethics teams.

3. Commitment to support the emergence of research projects (e.g., pump-priming grants)

- Implementation of SIRIC call for projects for emerging/high risk projects funding
- Follow-up and support of these projects' maturation into more ambitious grant applications
- Support for the creation of emerging research teams with integrated research programmes

Comments on criterion 3:

(Please feel free to use as much space as needed)

A number of projects have been funded to support project aligned with IRPs 1 and 2 involving at least 2 CARPEM teams. IRP 3 projects have not been funded through these calls (instead IRP3 has been funded according to staffing needs)

In addition, 4/13 PhDs funded to date, 2 Masters students funded. Prioritizing PhD funding going forward (part funding).

Post-doc research fellowships: 1 year funding for post-docs to initiate project while awaiting further funding. 7/19 funded so far and one renewed for extra year.

Specific recommendations for the 2nd period of the SIRIC designation:

(Please feel free to use as much space as needed)

Consider extending funding to projects involving IRP3

4. Commitment to a training programme in translational and integrated research

- Enlargement and reinforcement of the training opportunities on the specificity and constraints associated to the translational and integrated research (quality insurance, ethical and regulatory affairs, transversal management, etc)
- Programmes/activities proposed to scientists for training in the medical environment and programmes/activities proposed to clinicians for training in a scientific environment (bridges between basic science and clinical practice, and vice versa)
- Programmes/activities proposed to foster the continuum of research and integration of all disciplines, specially human and social sciences, epidemiology and public health

Comments on criterion 4:

(Please feel free to use as much space as needed)

The programme offers a relatively narrow training programme in partnership with other SIRICS - Inter-university diploma Molecular Medicine in Cancer – SOCRATE, CURIE and CARPEM open to oncology specialists in public and private sectors.

Specific recommendations for the 2nd period of the SIRIC designation:

(Please feel free to use as much space as needed)

Consider training programme needs of patients to support public engagement in research, debate and dissemination and training needs of those in IRP3.

5. Progress of the SIRIC multidisciplinary integrated programmes

For each integrated research programme, consider:

- Overall scientific quality and relevance of the programme

- Quality and quantity of the 1st achievements, the outstanding performances and the successful developments
- Robustness of the action plan for the 2nd period
- Anticipated outcomes in terms of production and dissemination of knowledge and practice
- Impact of the SIRIC label on the integrated research programme
- Joint actions with the other SIRIC research programmes

INTEGRATED RESEARCH PROGRAMME 1	
	Comments: *(Please feel free to use as much space as needed)* IRP1: Metabolism, genetics, immunity and environment Is there any connection with IRP3? Involvement of Medical Ethics team/patients in any aspects of this programme of research?
	Specific recommendations for the 2nd period of the SIRIC designation: *(Please feel free to use as much space as needed)* Consider opportunities to collaborate with IRP3, involvement of Medical Ethics team/patients in the programme of research
INTEGRATED RESEARCH PROGRAMME 2	
	Comments: *(Please feel free to use as much space as needed)* IRP 2: Cancer heterogeneity – a challenge for patient management Is there any connection with IRP3? Involvement of patients in any aspects of this programme of research?
	Specific recommendations for the 2nd period of the SIRIC designation: *(Please feel free to use as much space as needed)* Consider opportunities to collaborate with IRP3, involvement of Medical Ethics team/patients in the programme of research
INTEGRATED RESEARCH PROGRAMME 3	
	Comments: *(Please feel free to use as much space as needed)* IRP 3 – Dynamic consent and health democracy IRP3 addresses legal, ethical and human barriers encountered in modern translational research - 'ethical vigilance'. Main objective is to explore acceptance

	and feasibility of implementation of concept of dynamic consent for purpose of translational research in real life context of CARPEM. This IRP aims to build ethics by designing an e-dynamic consent platform and testing both feasibility and acceptability of the platform in real life. WP6 – relies on qualitative methodologies to explore interest of CARPEM patients in actively participating in translational research cohorts, their perception of the dynamic consent concept, the conditions of their acceptance of translational research practices such as sample and data sharing or data linkage, and their expectation for the communication of global data, personal data, secondary findings etc. WP6 will also investigate professionals' fears and expectations of these. WP7 and 8 – involves building a direct consent platform linked with the translational platform and test operability, acceptance by patients and professionals. WP9 – will test acceptance of data linkage in real life conditions (through CARPEM cohorts – Nutrinet-Sante study) - linking clinical data and data patients provide in NutriNet-Sante study WP10 involves coordinating and organising communication and debates with the public A number of problems have been encountered: Membership of ATEB had to be renewed – several members left, wanted to include locally treated patients. In addition, the legal and regulatory framework for research have been under revision in France since 2016. This has delayed establishing guidelines for the CARPEM Dynamic Consent platform The planned CARPEM LYNCH cohort is recruiting but only 35 patients to date. How many expected? Impact of Covid. Likely to reach planned number? 2 PhD students and a Masters student have been recruited to the ETRE team. There is some collaboration with other SiRIC IRPs but it is unclear how extensive this has been or whether there is scope to promote further collaboration. External collaborations are being developed. There are plans to disseminate to public, patients, patient representatives/advocates and clinicians through conferences, meetings, and workshops. These have been delayed by Covid. The first meeting of the ATEB has been delayed due to Covid. Future plans are to test in real life the acceptance, feasibility of implementation of dynamic consent in the context of translational research devoted to cancer in France. CARPEM presents this opportunity.
	Specific recommendations for the 2nd period of the SIRIC designation:

	(Please feel free to use as much space as needed) Develop strategic plan to optimize collaboration across IRPs. Develop contingency plans to proceed with ATEB and dynamic consent testing if restrictions continue due to Covid. Consider contingency plans if the cohort data collection is disrupted long term.

6. Availability of a sufficient patient population to support bench to bedside studies in all integrated research programmes

- Adequacy of the cancers/topics targeted in the integrated research programmes with the medical activity (sufficient number of patients)
- Sufficient rate of patient recruitment in the integrated research programmes : collection of biological samples, inclusion in clinical trials, etc

Comments on criterion 6:
(Please feel free to use as much space as needed)

Implications of Covid for meeting trial/cohort targets?

Specific recommendations for the 2nd period of the SIRIC designation:
(Please feel free to use as much space as needed)

Develop contingency plans if the cohort data collection is disrupted long term.

7. Effective integration between basic and applied scientists (e.g., clinicians, population scientists)

For each integrated research programme, consider:

- Experience and involvement of the programme leaders (scientific/medical expertise, management of teams, commitment to the programme, meetings organisation, etc)
- Relevant and justified selection of the members of the programme, representativeness of the multidisciplinarity
- Quality of the Intra-SIRIC collaboration (active participation, regular meetings, other animation activities), added-value of the multidisciplinary and integrated organisation of the programme
- Commitment of the multidisciplinary research team to achieve translational goals

Comments on criterion 7:
(Please feel free to use as much space as needed)

IRP3 and the Ethics team provide a real asset to the work programme as too does the involvement of patients in the research programme. For example, supporting plain language information materials for trials and designing the dynamic consent system to support studies across the IRPs.

Specific recommendations for the 2nd period of the SIRIC designation:
(Please feel free to use as much space as needed)

8. Commitment to develop and integrate human and social sciences, epidemiology and public health studies

- Strategy to develop and integrate human and social sciences, epidemiology and public health studies in the overall SIRIC objectives as well as in each research programme
- Activities effectively implemented by the SIRIC for the development and integration of the human and social sciences, epidemiology and public health studies and associated results

Comments on criterion 8:
(Please feel free to use as much space as needed)
IRP 3 is focused on ethics and health democracy and strong patient engagement. It is unclear how and where the activities of IRP3 and the teams involved eg ATEB link with IRP1 and 2. The earlier sections of the report suggested greater integration it would be good to know more about how this is taking place. The ATEB is a great asset.

Specific recommendations for the 2nd period of the SIRIC designation:
(Please feel free to use as much space as needed)

Consider how the IRP3 team, patients and ethicists can inform all aspects of the IRPs to optimize this valuable resource.

9. Involvement of patient advocates

- Consultation of patients' representatives for the SIRIC strategic decisions (governance and management structure)
- Involvement of patients' representatives in the research integrated programmes
- Participation of patients' representatives in activities related to the dissemination of knowledge and practice to the patients and the public

Comments on criterion 9:

(Please feel free to use as much space as needed)

Patients and their representatives are consulted as part of the CARPEM. There are patient representatives on the Steering Group. An encouraging addition to the management/governance structure is the Advisory Translational Ethics Board (ATEB) which gathers patients, patient reps, professionals together with ethicists. The ATEB oversees ethical and cultural dimensions of all CARPEM projects. Its role is to advise the steering committee to improve projects in terms of ethics, information, returned results to patients etc. Such discussions increase understanding of patient perspectives. The ATEB has not been able to meet due to Covid.

The CARPEM programme integrates ethical expertise in its governance and is developing ongoing empirical-ethical research to identify, support and fuel the debate about ethical issues encountered in real-life practice. This is a great strength of the programme.

Patients and their representatives are engaged in constructing an appropriate normative/ethical framework. Debate with patients and reps has led to:

1. Creation of a patient education programme to improve patient understanding of their disease, on research undertaken and how to manage different social aspects of their disease
2. Making information and support centre accessible to cancer patients, families, caregivers and researchers to better display and organise relevant info
3. Organise public events to discuss advances in cancer research

Specific recommendations for the 2nd period of the SIRIC designation:

(Please feel free to use as much space as needed)

Consider how the ATEB can function if restrictions continue in the longer term.

10. National and international synergistic collaborations as well as public-private partnerships

In each integrated research programme, quality of the extra-SIRIC collaboration:

- Effective national collaborations (including inter-SIRIC joint actions): regular meetings or teleconferences, operational exchanges, common publications
- Integration within the regional network: interaction and joint actions with the Cancéropôle (regional cancer hubs) or other regional structures
- Active international collaborations: regular meetings or teleconferences, operational exchanges, common publications
- Public-private partnerships (existence of collaborative contracts, licensing, creation of spin-off, etc)

Comments on criterion 10:

(Please feel free to use as much space as needed)

Plans for IRP3, eg to meet with ATEB, have been delayed due to Covid.

Specific recommendations for the 2nd period of the SIRIC designation:

(Please feel free to use as much space as needed)

Consider plans to continue collaborations in spite of continued restrictions due to Covid and continue to develop opportunities to collaborate with other IRPs and SIRICs. Could the valuable ATEB collaborate with other SIRICs where appropriate/feasible or support development of their own ATEB?

11. Dissemination of new knowledge and good practices resulting from the research towards health professionals and patients, incitation in technology transfer for economic development

- Appreciation of the networks supporting the dissemination programmes: public research institutions, public and private hospitals, charities, private companies, etc
- Efficiency of the activities performed for dissemination of knowledge and good practices towards professionals: information on new scientific knowledge, training on new practices (for screening, diagnosis, and treatment), knowledge transfer in management of quality of life, observance, inequalities, etc
- Efficiency of the activities performed for communication, dialogue and meetings towards patients and the public in order to share experience and progress expected before, during or after the disease
- Support and incentive measures in technology transfer for economic development of the research outcomes

Comments on criterion 11:

(Please feel free to use as much space as needed)

IRP 3 – has plans to disseminate (presumably findings and development across IRPs?) to public, patients, patient reps and advocates as well as clinicians through conferences, meetings and workshops.

These have been delayed due to Covid.

Specific recommendations for the 2nd period of the SIRIC designation:

(Please feel free to use as much space as needed)

Consider ways in which dissemination activities can continue in spite of continued Covid restrictions.

12. Ability to leverage funding and/or resources obtained as a result of an "excellent" designation

- Capacity of the SIRIC managerial structure to gain local and regional public funding (or equipment, facilities, etc)
- Capacity of the integrated research programmes to acquire other national or European important co-fundings
- Capacity of the SIRIC operational platforms and joint services to obtain innovative equipment or the associated funding

Comments on criterion 12:
(Please feel free to use as much space as needed)

CARPEM teams have raised 12M Euros during the past 2 years.

Specific recommendations for the 2nd period of the SIRIC designation:
(Please feel free to use as much space as needed)

Consider how IRP 3 research activities can be incorporated into funding bids across the IRPs as well as strategy for IRP3 led funding.

13. Global vision of the SIRIC, scientific directions, goals and perspectives for the 2nd designation period

- General understanding of the definition and objectives of the SIRIC designation
- Adequacy of the SIRIC activities with the initial objectives and workplan submitted in the application dossier for the designation in 2017
- Integration of the designation scientific committee recommendations
- Added-value of the SIRIC designation for the site and the local organisation
- Appropriateness of the SIRIC workplan and perspectives for the 2nd period of the designation
- Global expected impacts of the SIRIC at the end of the designation period regarding the 2 main objectives: improvement of integrated research and dissemination of knowledge
- Long-term vision beyond the end of the current designation (after 2022)

Comments on criterion 13:

(Please feel free to use as much space as needed)

The objectives of the IRP3 are clear. The ethical dimensions of new treatment and procedures are important to consider and the teams involved in IRP3 are well placed to do this in partnership with the ATEB and related groups.

The inclusion of IRP3, ATEB and Medical Ethics elements of the programme are an important and compelling asset that will add value to ongoing trials and patient care.

Specific recommendations for the 2nd period of the SIRIC designation:

(Please feel free to use as much space as needed)

Consider long term sustainability of the IRP3 team programme of research, ATEB and collaborations with IRP1 and 2 beyond the lifetime of the SIRIC.

Financial report 2018-2020

- Adequacy of the 2018-2020 financial plan with the SIRIC workplan
- Adequacy of the allocated budget to the general SIRIC managerial services
- Appropriateness of budget allocation between the different categories of expenses: staff, operating costs, equipment, etc
- Appropriateness of budget allocation between the integrated research programmes, the transversal platforms and the dissemination activities

Comments on the financial report:

(Please feel free to use as much space as needed)

The financial plans seem reasonable.

Specific recommendations for the 2nd period of the SIRIC designation:

(Please feel free to use as much space as needed)

Consider funding projects including IRP3 as a partner to strengthen the collaborations with IRP3.

General comments and recommendations

General comments on the SIRIC mid-term report and final recommendations for the 2nd period of the designation

(Please feel free to use as much space as needed)

This is a strong programme including an IRP dedicated to ethical issues. This is important as new treatments and procedures are developed. Involvement of patients in debates as they unfold will be an important element of translation from bench to bedside