Project Concept Template

Project Proposals for the RCA Programme 2024/2025

Part 1: Information Sheet

Project proposals for the RCA Programme 2024/2025 are to be prepared using the attached template and submitted BEFORE 31ST OF DECEMBER 2021. Completed templates will be reviewed by the RCA PAC in January 2022.

Resource documents required for developing Project Concepts can be found in the RCA web-site – (RCA Regional Office (rcaro.org)), under Projects/Resource Documents. (see below for the list of resource documents.

The Project Concept should be prepared in consultation with the stakeholders of the other participating GPs. Information on RCA stakeholders can be found in the RCA web-site (RCA Regional Office (rcaro.org)), under Projects/Project Information.

Please request access to the RCA Members Only web-site from RCARO (email: rcaro@rcaro.org) through your National RCA Representative if you do not already have access.

A proposal will be evaluated against the following criteria:

- Alignment of the objectives with priorities set out the RCA Regional Programme Framework (RPF) for 2024/25.
- Whether the project addresses a regional need.
- Whether nuclear technology is an essential component of the project.
- Whether outcomes and achievements of previous projects in this area of technology are considered.
- Does the proposal overlap or duplicate current or previous RCA projects?
- Is a convincing case made to justify further projects in this area?
- Is there a strong TCDC component?
- If the proposal is essentially an extension of previous projects in this area that have been implemented for more than 2 TC Cycles, does the proposal include arrangements for the transfer of project leadership to another GP?

List of Resource Documents on RCA web-site (www.rcaro.org)

1. Timeframe for preparation, review and approval of Project Concepts
2. Brochure on Logical Framework Matrix (Quick Reference Guide on Designing IAEA TC Projects)
3. RCA Regional Programme Framework for 2024-29
4. Details of RCA TC Projects implemented in 2007-2019
5. List of TC Projects being implemented in 2020/21 and projects approved for 2022/24
6. Recommendations on Technical Cooperation among Developing Countries (TCDC)

Please note that your National Representative will be reviewing the concept document to ensure that it has been prepared in compliance with the RCA and IAEA Criteria for TC Projects

Please contact the Chair of the RCA Programme Advisory Committee, Dr. Prinath Dias at prinathd@yahoo.com if you need assistance.

Part 2: Concept Template[1]

Title:

The title should be as concise as possible and should summarize the objective of the project.

Enhancing Capacity and Capability of Member States' Radiopharmaceutical Staffs through Education, Training and Practise for the Development of Diagnostic ^{18}F-based Radiopharmaceuticals

Analysis of gaps / problems / needs as applied to the RCA region:

Outline the major gaps /problems/specific needs to be addressed by the project (~ max 300 words):

Review the resource documentation and list any past RCA projects that have addressed similar problems/needs in this area of technology. Consider outcomes and achievements of previous projects, and avoid any overlap or duplication.

What are the major additional capabilities/skills in this area of technology that will be provided through this project (~ max 200 words).

This proposed project will contribute to the coordinated RCA project RAS6097 - Enhancing Capacity and Capability for the Production of Cyclotron-Based Radiopharmaceuticals. The radioisotope fluorine-18 (18F) produced in the cyclotron was chosen for its favourable properties (half-life, highest spatial resolution) for wide availability in nuclear medicine facilities. The discovery of peptides and small proteins that are only expressed in certain tumour stages or possibly cause neurological disorders (beta-amyloid plague) has opened the door for further investigations. However, due to the difficult conditions required for radiolabelling of ^{18}F in particular, it was considered unsuitable for complex formation with the peptides, proteins and oligonucleotides in question.

Recent developments in radiochemistry, particularly the aluminium fluoride (Al-^{18}F) technique, allow for shorter reaction times, more efficient radiochemistry, and a better economic approach. Nevertheless, preparing a target (bioactive molecule) with a chelating agent for complexation with ^{18}F and radiolabelling with Al-^{18}F is a challenge for a nuclear medicine technician. Therefore, we propose a platform to enhance the capacity and capability of Member State radiopharmaceutical personnel through education, training, and practise for the development of ^{18}F-based diagnostic radiopharmaceuticals for targeted peptide receptors such as fibroblast activation protein (FAP) and prostate specific membrane antigen (PSMA).

[1] If you have not been involved in drafting a concept before and if you are not fully acquainted with the RCA and its Programme you are encouraged to support advice and assistance from your RCA National Representative.

Overall Objective: (Required for the preparation of the IAEA Regional Programme Note)
State the overall long-term objective to which the project will contribute. This should reflect an impact related to the RCA Regional Programme Framework for 2024/29.
Problem and objective analysis using objective and problem trees is recommended. (See pages 9 and 10 of the Quick Reference Guide on Designing IAEA TC Projects in resource documents)

The proposed program aims to enhance the capacity and capability of Member State's radiopharmaceutical personnel through education, training, and practise for the development of ^{18}F-based diagnostic radiopharmaceuticals via:
1. human resource development – intensive training for nuclear medicine technologist (personnel involve in synthesis & radiolabeling, but not limited to radiopharmacist only) in Al-^{18}F radiochemistry and conjugating a target complexed with a bifunctional chelator.
2. expert support in the development of kit-based formulations if the nuclear medicine technologist is successful in the preparation of ^{18}F-bioactive molecules.

Project Outcome: (Required for the preparation of the IAEA Regional Programme Note)
The outcome is the planned result of a project, achieved through the collective effort of stakeholders and partners. It represents the change or improvement that occurs as a result of the project. Should be worded in past tense. (eg. The capability for ……developed)

RCA Projects are to be designed to have a Socioeconomic Benefit:
What is the potential socioeconomic benefit that would be realised from the project concept over a 5 to 7-year horizon?

The RCA project has contributed significantly to the initiation and development of diagnostic radiopharmaceuticals using the Al-^{18}F technique in the region. There are many centres or facilities in the region that are not fortunate enough to have a regular ^{68}Ge/^{68}Ga generator, but most of them have access to the radioisotope ^{18}F. ^{18}F can be easily produced in high yield in a medical cyclotron, while ^{68}Ga is produced by generators that provide limited activity per synthesis. Depending on the age of the generator, only one to four patient doses can be obtained per elution. With the Al-^{18}F technique, it is now possible to radiolabel targeting vectors (peptides and proteins) previously labelled with ^{68}Ga with ^{18}F. Radiolabelling could be achieved via the formation of ^{18}F in conjunction with a bifunctional chelator that has been covalently attached to the compound of interest using the Al-^{18}F chelator technique. This could fundamentally change the field of radiopharmaceuticals. As a result, the number of practitioners will increase, the skilled personnel will be improved through education and training, the dependence on foreign experts will be slowly reduced and finally the programme aims to create employment opportunities

Proposed Participating Government Parties:
List the Government Parties expected to participate in the project. Indicate target and resource GPs:

1. Republic of Korea
2. Thailand

Technical Cooperation among Developing Countries (TCDC) Project Component:
Please refer to the resource documents (RPF and Recommendations on TCDC)
Will the project design feature partnering arrangements between those advanced and those less advanced in the technology to be transferred through this project?
If so, list those expected partnerships.

The regional collaborative platform will not only provide optimal benefits for the further development of the niche radiopharmaceutical sector, but also support the sustainability of GPs in the radiopharmaceutical sector in meeting current and future development. All the expected participating RCS GPs have developed sufficient physical infrastructure (cyclotron and radiopharmacy laboratory), it is the human resources that are lacking especially in aluminium fluoride technology. National institutes with their infrastructure, facilities and human resource expertise will provide the necessary momentum for project implementation through a mix of technical cooperation between developing countries (TCDC) and partnerships between the advanced RCA GPs and those at a lower stage of development. These institutions would provide additional impetus in terms of physical infrastructure and human resource expertise for project implementation. National laboratories, academic institutions and technology experts in each GP will also provide support and augment their resources by participating as members of the national project team. RCA GPs with appropriate expertise and facilities will provide their expertise, experience and use of their national training programmes for the regional activities. It is expected that the successful implementation of the project will benefit all participating GPs in Asia.

Requirements for participation:
Indicate the minimum requirements that the counterpart institutions in Government Parties would need to meet in order to participate in this project.

The participating GPs should have at least established infrastructure / laboratory in radiopharmaceutical.

Stakeholder analysis and partnerships:
Briefly describe who are expected to be the end-users and principal beneficiaries of this project. Indicate whether the end-users contributed to development of the Concept.

In order to achieve the intended outcome and deliver the best possible output, the proposed project involves stakeholders from academic institutions, national institutions and private entities that have the technological background and experience to drive the project in achieving its objectives. They may represent the participating GPs as National Project Partners (NPC). The main responsibility of these stakeholders is to ensure the successful implementation of the project.

Have any extrabudgetary funding possibilities been identified?

The RCA GPs involved in this project have strong and strategic link that could enable the implementation of activities and adaptation of new technology or application at the national level.

Role of nuclear technology:

Indicate the essential nuclear technique that would be used and outline why it is suitable for addressing the problems/needs in question.

The project involves the use of radioisotopes to radioactivate the identified compound of interest (bioactive molecules).

Is this the only available technique that could be applied to address the problem/ need?

Other non-nuclear techniques, such as non-fluorinated (^{19}F), are also available for labelling the compound of interest. However, they cannot be used in positron emission tomography.

Does it have a comparative advantage over non-nuclear techniques?

Although other non-nuclear techniques are available for this task, the radiation-based method is still the best technique and has proven to be consistent throughout the radiolabelling and validation process.

Duration of the project:

Indicate the number of years required to complete the project.

4 years

Part 3: National Representative Endorsement for Project Concept

As the RCA NR of ***....(RCA GP)..... ,*** **I have reviewed the Project Concept thoroughly and confirm that it meets the following requirements:**

1. The objective of the Project Concept is aligned with priorities set out the RCA Regional Programme Framework (RPF) for 2024/25.
2. The project addresses a regional need.
3. Nuclear technology is an essential component of the project.
4. Outcomes and achievements of previous projects in this area of technology have been taken into consideration
5. There is no overlap or duplication with current or previous RCA projects
6. Further projects in this area can be justified (if relevant)
7. The Project Concept has a strong TCDC component

Signature:

Name: DR. ABDUL RAHIM BIN HARUN
Deputy Director
Research & Technology Development Programme
Malaysian Nuclear Agency
Ministry of Science, Technolofy and Innovation

Date: 27/12/2021