

Project Proposals for the RCA Programme 2020/2021 2nd Round Project Concept Template

Part 1: Information Sheet

Project proposals for the RCA Programme 2020/2021 are to be prepared using the attached template. Completed templates will be reviewed by the RCA PAC at the Meeting in Vienna being held 28 January to 2 February 2018.

- **PLEASE NOTE THAT ALL PROSPECTIVE CONCEPTS REQUIRE INFORMATION THAT IS LODGED ON THE RCARO WEBSITE (access is only required to the RCA information not the whole Members Only site).**
- **YOU WILL HAVE TO APPLY FOR A PASSWORD AND ACCESS CODE TO ENABLE ACCESS TO THIS INFORMATION.**
- **PLEASE GET ENDORSEMENT FROM YOUR NATIONAL REPRESENTATIVE FOR THIS ACCESS.**

The 2nd Round Concept Proposals will be evaluated against the response to the feedback you have received from RCA PAC on your 1st Round Concept Proposals as well as the criteria listed below:

- **Is its aims and objectives in line with priorities set out the RCA Medium Term Strategy for 2018/2023?**
- **Identify which elements of the MTS are being complied with.**
- **Why it should be a regional project.**
- **The essential role of the nuclear technology in the project.**
- **Does the proposal identify links to previous projects in this area of technology?**
- **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 to exploit the benefits from the earlier projects?**
- **Is there a readily available baseline against which to measure the effectiveness of the project?**
- **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 others?**

In addition to the above, please address the following specific questions:

Was this concept identified at the 46th RCA GCM as requiring merger with other similar concepts?	YES
If “YES” – was this concept prepared as a result of consultation with the other proposers?	YES
If “NO” - why was this not undertaken?	

(Please note that it is important to address all the dot points in the Concept Template.)

Your National Representative will be reviewing the concept document to ensure that it has been prepared in compliance with the RCA special requirements.

(Please be aware that, if your concept design does not take account of the special requirements for the RCA programme, it will be rejected.)

Part 2: Concept Template

Title:

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

Enhancing human resource capacity for qualified cyclotron based radiopharmaceuticals for disease control in the RCA Region

Compliance with the RCA Medium Term Strategy for 2018/2023:

All RCA projects have to comply with the RCA MTS for 2018/2023 - please refer to the MTS document.

- *Briefly indicate to which specific MTS priorities this project proposal contributes.*

This concept is in line with the strategic priority of the RCA MTS for 2018-2023 (C.2.2.-iii. Assist in the development and utilization of radio-labeled pharmaceuticals for imaging and treatment).

- *How will these be achieved?*

It will be achieved by building human capacity including education and training in terms of facilitating accessibility to quality radiopharmaceuticals required for medical applications. The expertise, knowhow, and experience will be shared among radiopharmacists, radiochemists, and cyclotron operators. The modalities of the project include Regional Training Courses, Expert Missions, and identification/sharing of information.

Overall Objective:

- *State the objective to which the project will contribute. (Note this has to be in line with the RCA MTS for 2018/2023. It should be a short description expressed as: To do)*

To enhance disease control through human resource capacity for qualified cyclotron produced radiopharmaceuticals for imaging and treatment.

It is in line with the strategic priority of the RCA MTS for 2018-2023, specifically C.2.2.-iii. Assist in the development and utilization of radio-labelled pharmaceuticals for imaging and treatment.

Radiopharmaceuticals are used in Nuclear Medicine modalities for diagnosing, staging, follow-up, and treating cancer. Besides cancer, radiopharmaceuticals are also used for diagnosis of other diseases such as cardiovascular disease, respiratory disease, dementia, etc. Therefore, it will eventually contribute to SDG 3.4 Reduce by one-third premature mortality from non-communicable diseases.

Proposed Participating Government Parties:

- *List the Government Parties expected to participate in the project.*

AUL, BGD, CPR, FIJ, IND, INS, JPN, KAM, ROK, LAO, MAL, MON, MYA, NEP, NZE, PAK, PHI, SIN, SRL, THA, VIE

NPCs will be designated by the participating Government Parties, but the followings are potential partners of recipient countries that have worked together for need identification and project design.

- BGD : Mr. Mohammad Anwar-Ul Azim, National Institute of Nuclear Medicine and Allied Sciences (NINMAS)
- FIJ : Ms. Shareena Shabnam Shah, Ministry of Health and Medical Services
- IND : Mr. Yuva Raj Nitin, RMC Tata Memorial Centre

- INS : Ms. Yulianti Susilo, Centre for Radioisotope and Radiopharmaceutical Technology
- KAM : Ms. Sann Chanthoubopha, Khmer Soviet Friendship Hospital
- LAO : Mr. Sonexay Rajvong, Mittaphab Hospital, Ministry of Health
- MAL : Mr. Suharzelim Bin Abu Bakar, Nuclear Pharmacy Unit, National Cancer Institute
- MON : Ms. Erdenechimeg Sereegotov, National Diagnostic & Treatment Center, Ministry of Health
- MYA : Ms. Ei Ei Khine, PET/CT and Cyclotron Center, Yangon General Hospital
- NEP : Mr. Surendra Subedi, Ministry of Science and Technology
- PAK : Ms. Haleema Zaneb, Pakistan Atomic Energy Commission
- PHI : Ms. Marie Grace Lucas Guieb, St. Lukes Medical Center
- SIN : Mr. Young Soon Tay, Singapore General Hospital
- SRL : Ms. Rajapaksha Kankanamge Dulanjalee Madhusa, Sri Lanka Atomic Energy Board
- THA : Ms. Natphimol Boonkawin, National Cyclotron and PET Centre, Chulabhorn Hospital
- VIE : Mr. Nguyen Quang Anh, Hanoi Irradiation Centre

- *Indicate each of those where you have baseline information on their requirements and needs:*

The following information of the above recipient countries has been shared during need identification as baseline information.

- No. of Cyclotron center (with/without GMP)
- No. of Radiopharmacist
- No. of Radiochemist
- No. of Cyclotron operator
- Clinically available radiopharmaceuticals from cyclotron (it will be compared with similar size cyclotron)
- Radioisotopes produced at cyclotron center (it will be compared with similar size cyclotron)

17 Member States have cyclotrons to produce radioisotopes or are scheduled to have at least one in public sector by 2019.

(AUL, BGD, CPR, IND, INS, JPN, ROK, MAL, MON, MYA, NZE, PAK, PHI, SIN, SRL, THA, VIE)

4 Member States are generally expected to install one before or during the project period.

(KAM, FIJ, LAO, NEP)

Cyclotron operation rate per year and QA protocol have also been discussed as possible baseline information although some countries did not have the nationwide information. It is believed that the information can be achieved at the Project Planning Meeting upon the initiation of the project.

Technical Cooperation among Developing Countries (TCDC) Project Component:

Review the documentation on line – www.rcaro.org/ ???.

- *Outline the TCDC strategies to be used in the project to enhance regional cooperation:*

According to the brief note on TCDC posted on the RCARO website, TCDC within the RCA Programme is defined as;

Activities that are components of an approved RCA Project that involves the sharing of developing countries' own expertise, technology, resources, facilities and other capacities with one another.

This project will contain an activity of defining regional resources and sharing it. It will review resources of participating Member States and define potential resource units classified by specific technical areas such as set-up of cyclotron center(including floor planning, commissioning), cyclotron operation, synthesis of

radiopharmaceuticals, QA/QC, and GMP. Technical exchange in the above specific technical areas among recipient countries will be promoted using the project modalities. Especially, Regional Resource Units (RRUs) in intermediate level group will be identified and encouraged to share their expertise and experience with the beginner group. Potential RRUs identified during need investigation are as follows.

- RMC Tata Memorial Centre (IND)
- National Cancer Institute (MAL)
- Pakistan Atomic Energy Commission (PAK)
- Singapore General Hospital (SIN)
- Hanoi Irradiation Centre (VIE)

Furthermore, any success story of developing countries will also be shared as a lesson and guidance for other developing countries.

- *Will the project design feature partnering arrangements between those advanced and those less advanced in the technology?*

Affirmative. The similarity in infrastructure or stage is generally expected to increase the benefits of technical exchange, especially in a modality of Expert Mission or on-line technical advice. Therefore, partnering arrangements based on the similarity of infrastructure such as the maker & size of the cyclotron, or partnering between GMP established site and GMP planning site will be encouraged. The above Regional Resource Units will take an active role in supporting beginner group under partnering arrangements, and will also be provided special attention and technical support as hubs by the advanced group.

- *If so, list those expected partnerships.*

RRUs in IND and MAL are expected to support neighbouring recipient countries such as NEP, SRL. RRUs in PAK, SIN will be able to provide experts for Expert Mission to other recipient countries. RRU in VIE had received intensive fellowship and a short-term training by ROK for 3 years in the past. Their expertise and experiences are evaluated enough to support other recipient countries such as LAO, FIJ, MYA. Recently, ROK established a partnership with MON in 2017 and have supported the establishment of the first cyclotron centre in Ulaanbaatar through procurement, technical advice and training. Mongolia's experience will be helpful to other countries that are planning to install a new cyclotron center in public sector.

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

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

Qualified radiopharmaceuticals are important in achieving good interpretable images for diagnosis of cancer, cardiovascular diseases, and respiratory diseases using hybrid imaging modalities of Nuclear Medicine, and also improving the effects of radionuclide therapy for cancer. Precise diagnosis is significant in early detection of diseases and decision of proper treatment methods. It eventually contributes to the control of Non-communicable diseases and also the development of national economy by reducing the loss of economic forces.

However, LMI countries do not fully benefit from the advancement of technology. It is caused by a lack of expertise and physical infrastructure, and also a shortage of skilled experts. Especially, the production of qualified radiopharmaceuticals requires experts in various fields such as chemistry, pharmacy, electronics, mechanical engineering, radiation, etc. Also, its multidisciplinary feature makes it more challenging for LMI countries to effectively produce good quality of radiopharmaceuticals.

The cyclotron centres of LMI countries of the RCA region have increased as follows and radiopharmaceuticals are more encouraged to be used along with the distribution of Nuclear Medicine technology.

-BGD(2), IND(14), INS(4), MAL(4), MON(1 in 2018), MYA(1), PAK(6), PHI(2), SIN(3), SRL(1 in 2018), THA(1), VIE(7)

-KAM, FIJ, LAO, NEP are generally expected to install one within the project period (by 2013).

Furthermore, among them, GMP(Good Manufacturing Practice) is mandatory in 6 MSs and recommendable in 1 MS, which shows more regional needs and higher possibility of TCDC on this high technical challenge.

The number of cyclotrons, kinds of produced radioisotopes, operational availability, protocol of QA/QC and its status of application can be used as a baseline for performance indicators.

- *Review the resource documentation and list any past RCA projects that have addressed similar problems/needs in this area of technology.*

According to the records of RCARO website and TC pride of PCMF website, there has been no RCA project on radiopharmaceutical production.

It is notable that there have been nine RCA projects since 1993 in Nuclear Medicine which clinically uses radiopharmaceuticals. It implies that the infrastructure and technology to use radiopharmaceuticals have been supported and it is proper time to support the effective production of qualified radiopharmaceuticals to enhance scientific capacity and maximize the impact of Nuclear Medicine application.

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

The project is intended to share expertise in all aspects & stages of producing qualified radiopharmaceuticals, ranging from a set-up of the new cyclotron center, cyclotron operation (focusing on economical production & increase of operational availability), synthesis of radiopharmaceuticals, QA/QC, GMP(Good Manufacturing Practice), and regulatory compliance in radiation safety.

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 minimum requirements are as follows.

- Cyclotron or a plan to have it in near future(within the project duration). It is recommended to be a public sector
- Radiopharmaceutical production facility installed or to be installed within the project duration in cyclotron center (GMP condition is not necessary for minimum requirements)
- Expert(s) who are or will be commissioned to operate cyclotron and/or synthesize radiopharmaceuticals

- *Indicate the status of expected participating Government Parties as “Resource” or “Recipient”.*

Resource institutions are required to have a minimum of 10 year experienced cyclotron operators, radiochemists, and radiopharmacists who are willing to share expertise and experiences.

They are expected to have a cyclotron center with hot cell and produce radiopharmaceuticals daily for clinical use.

GMP is not unanimously agreed among experts to be necessary for all recipient countries. Therefore, cyclotron centers with GMP condition in resource countries will provide training for only those recipient countries that have a plan to install GMP facility.

Stakeholder analysis and partnerships:

- *Briefly describe who are expected to be the principal beneficiaries of this project and any role that will be defined for them in the project.*

The principal beneficiaries who will be trained by project activities are radiopharmacists, radiochemists, and cyclotron operators involved in daily production of radiopharmaceuticals. The responsibility and role defined for them in the project are as follows.

- Cyclotron operator : operation of cyclotron, operational availability, management of maintenance, safety
- Radiochemist : economical/effective production of radioisotope, synthesis of radiopharmaceuticals, GMP
- Radiopharmacist: quality control/quality assurance of radiopharmaceuticals, GMP

The project will also benefit Nuclear Medicine technologists and physicians with better quality of image. It will help clinicians to decide optimal treatment method using precious diagnosis and eventually benefit patients of cancer, cardiovascular disease, respiratory disease, and dementia.

Health care policy makers, Science & Technology Ministry, and radiation safety officials are also related in terms of policy design.

As implied in the list of potential participating institutions and recommended in minimum requirements, this project is intended to strengthen the capacity of public sector for introducing new technology in the country or providing important radiopharmaceuticals for public good in the field of installing cyclotron center, operating cyclotron more effectively, introducing new radioisotope, and synthesizing a better quality of radiopharmaceuticals. Therefore, private incorporates only running cyclotron and selling radioisotope are not main stakeholders.

- *Have any extrabudgetary funding possibilities, sponsors and partners been identified?*

ARCCNM(Asian Regional Cooperative Council for Nuclear Medicine) and WCI(World Council on Isotope) are identified technical partners for this project. Extrabudgetary funding possibilities have been explored, but not confirmed yet.

- *Have any sponsors/partners been involved at the concept stage?*

ARCCNM(Asian Regional Cooperative Council for Nuclear Medicine) have been involved at the concept stage. WCI(World Council on Isotope) has provided information on the status of radioisotope utilization.

- *Have any sponsors/partners made firm commitments of support at this stage?*

Technical support including experts is committed by ARCCNM, but no commitments for extrabudgetary funding.

- *Have any sponsors/partners expressed firm commitments to extrabudgetary support?*

Not yet identified.

Role of nuclear technology:

- *Indicate the essential nuclear technique that is planned be used in this project.*

Radiopharmaceutical is a drug compound or other material labelled or tagged with a radioisotope through pharmaceutical processing, administered to the patients for Nuclear Medicine scans and therapy. Qualified radiopharmaceuticals are important in achieving good interpretable images for diagnosis of cancer, cardiovascular diseases, respiratory diseases, and dementia, and also improving the effects of radionuclide therapy for cancer. It belongs to the TC Field of Activity 28 (Radioisotopes and radiopharmaceuticals production for medical applications).

- *Outline why it is suitable for addressing the problems/needs in question.*

The project is intended to share expertise in all aspects & stages of producing qualified radiopharmaceuticals such as a set-up of the new cyclotron centre, cyclotron operation (economical production & increase of operational availability), synthesis of radiopharmaceuticals, QA/QC, GMP and regulatory compliance in radiation safety.

- *Is this the only available technique?*

Affirmative for specific purpose. Radiopharmaceuticals are the only medicine used for non-invasive hybrid imaging modality to show molecular biology details. There are other techniques for disease diagnosis, but they are different from radiopharmaceutical based nuclear medicine scan. For example, biopsy is invasive test. CT or MRI shows organic anatomic changes, not molecular biology information. Each is still widely used as an important tool for diagnosis, but for different purpose according to its function and condition.

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

Affirmative for specific purpose. Radiopharmaceuticals enable non-invasive examination of diseases comparing to other invasive ones. In addition, hybrid imaging modality using radiopharmaceuticals can detect smaller size of cancer comparing to CT or MRI and also show biological change in follow-up because it provides molecular biology information.

Duration of the project:

- *Indicate the number of years estimated to be required to complete the project.*

4 years (2020~2023)

Part 3: National Representative Endorsement for Project Concept

I have endorsed the proposer to have access to the RCARO web page for the resource documentation necessary to complete the attached concept document.

This 2nd Round Concept meets the RCA project requirements and I endorse it as a priority for the RCA Programme 2020/2021.

Signed:



Chung won LEE

Director, Ministry of Science and ICT, Republic of Korea

Date: 15 January 2018