CALL FOR PROPOSALS

Coordinated Research Project (CRP) on
“Dosimetry in Radiopharmaceutical therapy for personalized patient treatment”
(E2.30.05)

Background information

Radiopharmaceutical therapy (RPT) has demonstrated unique therapeutic advantages in the treatment of an increasing number of cancers. As with other treatment modalities, there is related toxicity to a number of organs at risk. The clinical benefit of performing dosimetry has now been demonstrated for a number of nuclear medicine therapies. However, propagation of dosimetric methods into nuclear medicine practice remains slow and considerable uncertainties in absorbed dose calculations still exist. Harmonized dosimetric protocols and methodologies should guide a personalized patient treatment with the aim of improving efficacy and reduce toxicity.

The International Atomic Energy Agency (IAEA) is about to initiate a CRP on Dosimetry in RPT to support the standardization and dissemination of dosimetric methods in nuclear medicine therapy. The CRP will assist Member States in testing and adopting harmonized dosimetric protocols and to assess the typical accuracy with which dosimetry can be reached in nuclear medicine practice. State of the art research in the field will be implemented, with a direct impact to both the clinical services and the research potential of the Member States.

Overall Objective

The overall objective of this project is to enhance the capabilities of Member States to incorporate dosimetry in RPT practice. The ultimate benefit will be to patients receiving individualized RPT so as to make this treatment modality safer and more effective.
Specific Project Objectives

1. Establish an understanding of tools and methods available for dosimetry of RPT
2. Assess and investigate ways to improve the achievable accuracy of tumour and normal tissues absorbed doses
3. Create scientific networks with expertise in dosimetry for RPT that will remain active after the completion of the CRP
4. Support participating institutes to become reference centres on RPT for their Member States
5. Identify the advantages of implementing dosimetry in terms of reducing toxicity and improving tumour response

Project Activities

Under the framework of the CRP participants are expected to contribute to the coordinated research project by participating in a common activity and also in individual research activities. Both common and individual research activities will be performed by Research Contract holders in collaboration and under the guidance of Research Agreement holders.

Common activities
1. Identify software and analysis methods appropriate for dosimetry of RPT.
2. Perform all the tasks needed to estimate tumour and normal organ absorbed doses on data sets that are:
   a. Provided by Agreement holders
      i. Clinical
      ii. Simulated
   b. Collected locally by Contract holders
3. Provide a written report, identifying the most challenging steps, or those that are subject to the greatest uncertainty.
4. Select one or more patient cases for whom dosimetry has been calculated at all the participating sites and assess the variability in dose determination.
5. To help disseminating each site’s experience, prepare tutorials on dosimetry for RPT (e.g., in the form of slide sets, videos, web pages).

Common activity 1 should include:
1. Software currently being used locally (either locally developed, open source or commercial).
2. Other software available for free (open source software).
3. Other commercially available software.
Common activity 2 will involve the following tasks:
1. For 2a, reconstruct the images (depending on local capability), or receive already reconstructed and calibrated 3-D image data; for 2b, local image reconstruction is expected.
2. Register images acquired at different time-points to a common reference image set.
3. Segment tumours and normal organs by drawing volumes of interest (VOIs) at each time point.
4. Integrate the activity (activity concentration) in VOIs over time.
5. Calculate absorbed doses to normal tissue and tumours.

Common activity 4 will involve pooling the dosimetry results from all of the centres and calculating the variability in dose estimates for selected organs and tumours.

Individual research activities

Participants are encouraged to propose research activities in the field of dosimetry for RPT, including activities common to all participants and individual research activities that are of local interest and could benefit from the support of experienced researchers. Possible individual research activities could include an evaluation of:
1. The pros and cons of different software packages
2. Different reconstruction approaches
3. Different segmentation approaches
4. Different integration/fitting approaches
5. Different dose calculation algorithms
The applicant should indicate relevance to their current research or clinical activities of the proposed individual research project.

Proposed individual research activities will be reviewed and possible collaborations among different research teams will be explored during the first Research Coordination Meeting (RCM).

Requirements for the applicants

1. **Regular RPT workload** (number and type of treatments per year should be specified in the proposal); experience with systemic RPT (in particular with Lu-177 labelled radiopeptides) will be an asset.
2. Applicants should have **access to calibrated activity measurement devices**, including imaging systems.
3. Participating institutions must have **established QA/QC procedures in place**, and provide corresponding description.
4. Applicants must submit a list of available equipment (e.g. dose calibrators, gamma cameras, SPECT/CT, PET/CT, QC phantoms).

5. Applicants must submit a list of available software (open source, commercially available or locally developed). Specify the vendor and workstation (if relevant) and the application addressed by the software (e.g., registration, segmentation, time-activity curve fitting, etc.).

6. Due to the nature of the CRP, the CSI must be a medical physicist experienced in radiopharmaceutical dosimetry and/or nuclear medicine therapy. The secondary CSI should preferably be a nuclear medicine physician. Additional team members relevant to the success of the proposed project should be listed.

7. Applicants must submit a proposal for an individual research project on RPT dosimetry.

8. Applicants must comply with their institutional legal and ethical requirements.

9. As the basic language of the CRP will be English, participants must have sufficient proficiency to deliver and follow presentations and express themselves in this language without difficulty.

**Evaluation criteria for the submitted proposals**

The submitted proposals should include all the necessary information related to the available infrastructures and human resources of the institution, as well as the details of the proposed research, as described in the requirements for applicants, in order to allow proper evaluation of the proposal. Priority will be given to CSI and secondary CSIs with experience in nuclear medicine therapy and RPT dosimetry. Applicants will be asked to complete an on-line survey and to take part to a teleconference, in case additional information or clarifications are needed for the selection process.

The main criteria for the evaluation of the proposals are:

1. **Originality** of the individual research proposal (15%)
2. **Relevance** of the individual research proposal towards enhancing or expanding the local facilities' current procedures (15%)
3. **Impact** of the research project for the discipline, overall (10%)
4. **Appropriateness** of the facility (including research team) (20%)
5. **Scientific and clinical background of the applicants** (20%)
6. **Potential for success** within the time limit of the CRP (20%)

**Guidelines for authorship and acknowledgments of deliverables**

Authorship for peer reviewed publication will be based on the guidelines recommendations from the International Committee of Medical Journal Editors on authorship [2009]
All deliverables generated under this CRP must include acknowledgement to the IAEA CRP and corresponding project number.

**Research Contracts and Agreements**

A maximum number of six Research Contracts and six Research Agreements are expected to be awarded under this CRP.

**Research Contracts** are generally awarded to institutions in developing countries or countries in transition insofar as they can effectively carry out the research. Each Research Contract awarded in the framework of this CRP is associated with an annual financial support of 4,000 euros per year for a period of 3 years (subject to submission and favourable review of an annual progress report).

**Research Agreements**, which are not associated with any financial support, are generally awarded to institutions in developed countries and are awarded for the entire duration of the CRP. All participants of the CRP are eligible to attend the Research Coordination Meetings at the Agency’s expense.

**Applications –Duration**

Information on the IAEA Coordinated Research Programme and how to apply for Research Contracts and Research Agreements can be found at [http://www-crp.iaea.org/](http://www-crp.iaea.org/).

Proposals should be officially submitted by **April 30, 2017** directly to the IAEA’s Research Contracts Administration Section (**research.contracts@iaea.org**).

The expected duration of the CRP is 3 years (2017-2020) and the first Research Coordination Meeting is initially planned for **November 27-December 1, 2017** in Vienna, Austria.

For further information related to this CRP, potential applicants could contact Mr Gian Luca Poli (**G.L.Poli@iaea.org**) and Harry Delis (**H.Delis@iaea.org**), Project Officers, Dosimetry and Medical Radiation Physics Section, Division of Human Health, Department of Nuclear Science and Applications, IAEA.