Call for user projects

Guide for applicants

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Revision History

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2.0	21 Jul 2022	Kirsten Leufgen, Iris Dimbwadyo, Peter Ulrich	Second version, released at the occasion of call PRISMAP-2022-2

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Abbreviations and definitions

Good laboratory practice (GLP)	PRISMAP follows the OECD Principles of Good Laboratory Practice (GLP) to ensure the generation of high quality and reliable test data related to the safety of industrial chemical substances and preparations. This quality system is concerned with the organisational process and the conditions under which studies are planned, performed, monitored, recorded, archived and reported.
Good manufacturing practice (GMP)	Good Manufacturing Practice (GMP) is a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product. GMP covers all aspects of production from the starting materials, premises, and equipment to the training and personal hygiene of staff. Detailed written procedures are essential for each process that could affect the quality of the finished product. There must be systems to provide documented proof that correct procedures are consistently followed at each step in the manufacturing process - every time a product is made. GMP grade is required for medical applications in human.
H2020	The European Union's Horizon 2020 research and innovation programme
Non-carrier added (n. c. a.)	No carrier atoms have been added and precautions have been taken to minimize contamination with stable isotopes of the element in question. It does not necessarily mean, however, 100 % isotopic abundance.
Preclinical grade	A purity grade compatible with preclinical studies which corresponds to research grade with suitable pH, activity concentration and other necessary conditions.
Research-grade	Purity grade suitable for research work not involving (pre-)clinical studies
Users	The term Users refers to the group created by the main applicant and the co-applicants. Users are led by the main applicant. *User project* refers to the project proposed by the users.

PRISMAP Consortium members

CERN	European organization for nuclear research
NPL	National Physical Laboratory
PSI	Paul Scherrer Institut
CEA	Commissariat à l'énergie atomique et aux énergies alternatives
IST-ID	Associação do Instituto Superior Técnico para a IST-ID Investigação e Desenvolvimento
DTU	Danmarks Tekniske Universitet
CHUV	Centre hospitalier universitaire vaudois
GANIL	Grand Accélérateur National d'Ions Lourds
SCK CEN	Studiecentrum voor Kernenergie / Centre d'étude de l'énergie nucléaire
ARRONAX	Groupement d'intérêt public ARRONAX
ESS	European spallation source ERIC
TUM	Klinikum rechts der Isar der technischen Universität München
KULeuven	Katholieke Universiteit Leuven
MedAustron	Entwicklungs- und Betriebsgesellschaft MedAustron GmbH
SCIPROM	SCIPROM Sàrl
MUI	Medizinische Universität Innsbruck
ILL	Institut Max von Laue - Paul Langevin
JRC	JRC -Joint Research Centre- European Commission
NCBJ	Narodowe Centrum Badań Jądrowych
GSI	GSI Helmholtzzentrum für Schwerionenforschung GmbH
LU	Latvijas Universitāte
INFN	Istituto Nazionale di Fisica Nucleare
UiO	Universitetet i Oslo

Summary

This document is the official guide for applicants targeting the PRISMAP call for user projects.

It describes the available PRISMAP services and how to apply for them. Conditions for applicants and user projects, evaluation criteria and the selection procedure are given. The user application form is detailed and the expected proposal contents is described.

In preparation of their proposal, we invite all applicants to get in contact with us via our help desk to discuss their user project idea.

1. What we offer

PRISMAP is the European medical radioisotope programme on the production of high-purity radionuclides by mass separation. We federate a European consortium of the key intense neutron sources, isotope mass separation facilities and high-power accelerators and cyclotrons, with leading biomedical and healthcare research institutes in the active translation of the emerging radionuclides into medical diagnosis and treatment.

PRISMAP offers a single-entry point to researchers who are seeking innovative radioisotopes of high purity grade for medical applications. Our aim is to enable and accelerate early phase research on radiopharmaceuticals, targeted drugs for cancer, theranostics and personalised medicine. Through our web access platform, interested researchers may discover all available radioisotopes and services offered by PRISMAP, sorted based on the available radionuclides along the periodic system of the elements, by geographical location of the facilities, and along the stages for innovative radiopharmaceutical development up to first in-human studies.

We offer access to the following goods, facilities, and services:

- Production and delivery of high-purity grade radioisotopes for medical research
- Access to a selection of medical research laboratories to perform the associated research
- Preclinical research techniques in self-service or fully performed as a service

Access is granted for user projects which are selected on an excellence base. To promote cross-border access, only transnational access is granted.

Delivery of radioisotopes EXCLUDES packaging and shipping costs. Travel, subsistence, and local accommodation costs are NOT covered under PRISMAP.

2. Can you apply?

2.1 General conditions

- To foster cross-border exchanges, the European Commission funding all PRISMAP activities requires that access to PRISMAP services is transnational. The main applicant and the majority of the co-applicants must work in a country other than the country(ies) where the installation(s) providing the services are located. The European Organization of nuclear research (CERN) and the Joint research centre - European Commission (JRC) are international organisations and access is considered transnational from all user countries. If the main applicant or the majority of the applicants come from country X, and there are costs for a series of services provided by different facilities in different countries, only those services taking place in countries other than country X are eligible for funding, but not those taking place in country X.
- Access for users with a majority of the applicants not working in an EU or associated country is limited.
- Users need to be affiliated to an academic research institution, to a non-academic research institution, to a research hospital, or to the research department of an SME.
- The research project must relate to the use of radionuclides in medical applications. The finality of the research project should be to improve the diagnosis or treatment of of human disease.
- The requested radionuclides and biomedical application services should be available from at least one of the PRISMAP infrastructures. Expression of interest for innovative radionuclides that are not yet available from PRISMAP are also welcomed to help guide our developments and broaden our offer.
- The PRISMAP partner who is in charge of providing a radionuclide shall provide the selected users free of charge with the PRISMAP radionuclide, as long as the costs do not exceed the PRISMAP budget available, except for radionuclide packaging and shipping costs. The selected users have to provide their authorisation to receive the radionuclides at the activities requested.

- The service provider (i. e. the PRISMAP partner who is in charge of performing the medical application or providing laboratory access to the chosen infrastructure) shall provide the selected users free of charge access to the infrastructure managed by it, including all the logistical, technological and scientific support as well as specific training that is normally provided to external users of the infrastructure.
- Medical application services for all users will be reimbursed according to the normal internal rules and procedures of the infrastructure, as long as the total costs do not exceed the PRISMAP budget available, except for radionuclide packaging and shipping fees.
- Users should abide by the normal working practices, and health and safety regulations of the infrastructure while present at the site.
- The radionuclide provider shall not be liable for any claim that may arise from the use of the radionuclide or medical facility. The use of radionuclides and presence of users in the facility occurs at their own risk. Neither the personnel of the facility nor the infrastructure itself accept liability for the damage or loss of any instruments, apparatus and test equipment of the users whether or not such damage or loss was caused directly or indirectly by their negligence. Visiting users will ensure they have appropriate insurance, including personal health, accident cover and personal liability. The facility may conclude an access contract with the main applicant.
- All applicants must comply with the ethics and dissemination rules detailed below.
- Before the onset of the user project, a user agreement will be signed stipulating the legal framework of the collaboration based on the conditions summarised here, in Section 2 of the present Guide for Applicants.

2.2 Dissemination rules

Only users that are allowed to disseminate the results which they have generated under the project may benefit from the access, unless the users are working for SMEs.

For each user project a publishable project summary and a publishable summary of the results will be published on the PRISMAP website. We strongly encourage further publication of results in journals or on conferences.

All participating PRISMAP facilities shall be acknowledged in the publication. Acknowledgement and co-authorship of PRISMAP staff members who participated in the experiment shall be considered according to the research field best practices and verified with the PRISMAP technical manager before any publication.

Users must comply with H2020 dissemination rules, i.e. acknowledge that their work was financially supported by the European Union's H2020 Research and Innovation Programme and grant open access to resulting publications and related data.

Dissemination shall take place only once legitimate interests regarding intellectual property have been safeguarded. A maximum publication delay of 90 days may be granted for this purpose.

2.3 Ethics regulations

For activities of the **users** of the translational medical application hubs, **ethical issues may apply**. In particular, animal studies or **first-in-human studies** may be included. Before the onset of such activities, the users will fulfil all related ethical requirements and sign a PRISMAP statement that their research complies with these requirements. The two organisations, which offer access to first-in-human studies in the frame of PRISMAP (TUM and CHUV), have ethics departments in place to accompany the users in this endeavour. As part of the access procedures the related ethical requirements will be reviewed, compliance confirmed and documentation collected by the PRISMAP Ethics Manager, **David Viertl (CHUV)**, where necessary with the help of external ethics advisors.

3. How to apply

Applications are submitted online at any time via the PRISMAP web access platform and are reviewed twice a year. The cut-off dates are indicated there.

The user application form consists of two parts: Part A is completed through online forms and includes the request for radionuclides and application services as well as administrative information. Part B includes a description of the proposed scientific user project, to be uploaded as a PDF file.

3.1 The online form (Part A)

The online application form consists of the following fields:

- **Selection of requested services**
  - Medical radionuclides
    - Which radionuclide would you like to use?
    - Quality. All available qualities of the selected radionuclide are listed, please tick all required for your user project.
      - Research grade
      - Preclinical
      - GLP
      - GMP
    - Activity amount required
    - Is non-carrier-added quality required?
    - Are further PRISMAP radionuclides required? (if any, max 3 – same questions)
    - Details about deliveries required
  - Biomedical application
    - None
    - Application in cells and tissues
    - Application in animals
    - Application in humans
    - Other (radiopharmacy, technological development …)
- **Description of the project**
  - Title of the project
  - Publishable summary (max. 2000 characters including spaces)[1]
  - Key words
  - Estimated project duration
  - Desired start date
  - Upload of part B
- **Administrative data**
- Main applicant (Name, affiliation, position, phone number, email address)
- Co-applicants (Name, affiliation, position, email address) (if any, max 3)
- Additional contact persons (Name, affiliation, position, email address)
  - For radioactive good matters/transportation
  - For radionuclide handling and reception authorization
  - For ethical and regulatory issues

[1] Only the abstracts of the user projects that are selected for funding are actually published.

3.2 The scientific project (Part B)

3.2.1 Overview

Part B of the proposal should be structured as follows:

- Cover page
- Section 1: Scientific excellence
- Section 2: Project implementation
- Section 3: Expected outcome
- Section 4: Short description of the research team
- Section 5: Co-funding beyond PRISMAP
- Section 6: References

Sections 1-6 are limited to a **total number of 10 pages in A4 format,** excluding the cover page and Section 6.

No specific template is provided for Part B. Please follow the structure outlined above. The proposal shall be written in English. Please use a minimum font size of 11 points, standard character spacing and a minimum of single line spacing. This applies to the body texts. Text elements other than the body text, such as tables, headers, foot/end notes, captions, formula's, may deviate, but must be legible. The page size is A4, and all margins (top, bottom, left, right) should be at least 20 mm (not including any footers or headers).

The proposal part B should be submitted as a single PDF file with a maximum file size of 5 MB.

3.2.2 Cover page

On the cover page, please include the full title, the call identifier, name and email address of the lead participant.

3.2.3 Section 1 – Scientific excellence

Please provide in this section your motivation and the project objectives. What is your added value of applying to PRISMAP? In how far would you have access to radionuclides or their medical application in your own country?

Describe in how far the project goes beyond the state of the art. Summarise the proposed methodology, including the underlying concepts, models, assumptions.

3.2.4 Section 2 – Project implementation

Please describe the work plan incl. timeline (Gantt chart), description of work to be carried out, deliverables, risk assessment and mitigation measures. Detail and justify the number of radionuclide deliveries required over the project duration.

3.2.5 Section 3 – Expected outcome

Please describe the expected outcomes of your user project. What will be the impact in scientific, economical and societal terms? How and by whom will the results be used? Describe the measures for a plausible path to commercialisation and/or clinical use.

3.2.6 Section 4 – Short description of the research team

Please briefly describe your research team, including possible co-applicants. Describe the relevant background and experience of the team members, available infrastructure, and previous or ongoing related projects.

3.2.7 Section 5 – Co-funding beyond PRISMAP

Please describe other grants or projects which support and co-fund your proposed PRISMAP user project.

3.2.8 Section 6 – References

Provide here references which are relevant as background for your user project or support your previous related activities. Please also provide the links to the open access version of the references.

4. What will be assessed?

Projects will be evaluated based on eligibility (see participation requirements above, in Section 2) and scientific merit through independent peer review by a User Selection Panel.

Feasibility and logistical requirements will be pre-screened based on part A, involving also the PRISMAP facilities concerned.

The User Selection Panel consists of six members of the PRISMAP consortium who are knowledgeable about the technical feasibility of the request and six external international scientific experts in the research fields of relevance to PRISMAP. The members of the User Selection Panel are presented on the PRISMAP website.

Scientific merit will be measured based on Sections 1-4 of the proposal part B as outlined in Section 3 above. A maximum of five points will be attributed to each Section (1: Insufficient, 2: Poor, 3: Satisfactory, 4: Good, 5: Excellent). All user projects reaching an overall threshold of 14 out of 20 points are in principle eligible for PRISMAP funding and will be invited to hearings based on which the evaluation of all proposals of a user call will be finalised and proposals will be ranked and selected for funding.

The project selection will also consider if

- the users have not yet benefitted from the services,
- the project has the potential to attract the additional financial support required to fund the remaining project costs beyond PRISMAP services,
- the users are working in countries where radionuclide services are not readily available.

Evaluation results will be made available within two months after the cut-off date of a call.

The user project needs to be started at the latest 18 months after selection for funding.

References

- **H2020 Ethics self-assessment:** https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf
- **H2020 guidance on dissemination and communication:** https://ec.europa.eu/research/participants/docs/h2020-funding-guide/grants/grant-management/communication_en.htm
- **H2020 guidance on open access and data management:** https://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/open-access-dissemination_en.htm