Deliverable D1.2

Standardised access procedures

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101008571 (PRISMAP). This document reflects only the view of the author(s). The Agency is not responsible for any use that may be made of the information it contains.

Project Acronym	**PRISMAP**
Project Title	**The European medical radionuclide programme: Production of high purity radionuclides by mass separation**
Grant Agreement No.	**101008571**
Topic	**INFRAIA-02-2020: Integrating Activities for Starting Communities**
Project start date	**01 May 2021**
Nature	**Report**
Dissemination level	**Public**
Due date	**M24, extended to M36**
Date of delivery	**M36**
Lead partner	**SCK CEN**
Contributing partners	**ARRONAX, CERN, SCIPROM, MRI TUM, CHUV, ILL, PSI**
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Revision History

Version	Date	Author	Comment
0.1	26.03.2024	Lead: Ruth Vreys Charlotte Duchemin, Ferid Haddad, David Viertl, Calogero D'Alessandria, Zeynep Talip, Ulli Köster	Final draft
0.2	02.04.2024	Kirsten Leufgen	Consortium internal review
0.3	18.04.2024	Ruth Vreys	Response to internal review Revision and completion according to PRISMAP style and editing guidelines
0.4	22.04.2024	Véronique Gobry	Review and formatting
0. 5	23.04.2024	Kirsten Leufgen, Thierry Stora,	Final revisions. Version for review by the PRISMAP General Assembly
0.6	24.04.2024	General Assembly	General Assembly review
	28.04.2024	Thierry Stora	Review by the coordinator
0.7	30.04.2024	Ruth Vreys, Charlotte Duchemin	Implementation of the suggestions proposed by the General Assembly
1.0	30.04.2024	Kirsten Leufgen	Final version, approved by the General Assembly

Contents

Abbreviations, Participant short names

Abbreviations

ALARA	As Low As Reasonably Achievable
FAQ	Frequently Asked Questions
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
NA	Networking Activity
NDA	Non-Disclosure Agreement
PRISMAP	European Medical radionuclide Program
SME	Small and Medium-sized Enterprise
TNA	Transnational Access Activity
USP	User Selection Panel
WP	Work Package

Participant short names

CERN	European organisation 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

Radionuclides can be produced at different facilities such as research reactors or accelerators, followed by subsequent purification steps, e.g., in adequate radiochemical facilities. However, often there was no standardised way for interested users to receive ("access") such radionuclides or services.

Also, transnational access to (bio)medical research facilities is very challenging as rules and requirements related to radioprotection, preclinical and clinical studies often vary significantly from one country to another.

PRISMAP, the European medical radionuclide programme, brings together key production facilities (WP2-TNA2) and leading medical research facilities (WP3-TNA3) across Europe. These partners will make part of their facilities or the services provided by these available via PRISMAP. As such, the PRISMAP consortium can provide a sustainable source of high purity grade new radionuclides as well as access to translational research centres that can operate with these radionuclides.

One of PRISMAP's objectives is to develop a common web interface and entry port for the starting European nuclear medicine research community. WP1-TNA1 has developed a PRISMAP public website where the available radionuclides, the production facilities, and the translational medical research facilities with their services are presented. Access to these PRISMAP services is organised via PRISMAP calls for user projects. Individuals, groups and organisations are invited to submit a project application using the online access platform. Four calls for projects have been launched since the beginning of PRISMAP. Over the years, several adjustments have been made to the application procedure. Optimising this process is crucial for enhancing efficiency, reducing complexities, and ensuring a more streamlined and accessible user experience. The objective of the deliverable **D1.2.'Standardised access procedures'** is to establish a common PRISMAP access process by standardising the access procedures for all PRISMAP production facilities (TNA2) and biomedical facilities (TNA2), ensuring a smooth and efficient user experience.

This document starts with an i**ntroduction** of PRISMAP and the scope of this deliverable. The second chapter specifies what **PRISMAP access** entails. It contains an overview of the established access rules, a flow chart that visualises the various steps involved in the access process and a concise description of all the steps. The next chapter covers the **User Agreement** that is to be signed once a project is selected for PRISMAP funding. As PRISMAP facilities operate under specific access conditions, this agreement describes the rights and responsibilities of both users and the assigned PRISMAP facility. By adhering to these agreed-upon terms, users can ensure a smooth and productive collaboration with PRISMAP facilities. Upon the completion of a project, users are required to submit a comprehensive **User Project Report** which is covered in chapter four. This report serves as a summary of their research, documenting key findings, methodologies, challenges encountered and feedback to the PRISMAP consortium. The subsequent chapter lists the **PRISMAP call optimisations** that have been done in between the PRISMAP calls to improve the project application. **Lessons learned** are captured in chapter six and include feedback from the User Selection Panel as well as the production and biomedical facilities. This section provides valuable insights into what worked well and what didn't during the process. By understanding these lessons, areas for improvement can be identified and valuable knowledge and experiences can be transferred to future calls, preventing the repetition of past mistakes. In the final chapter **recommended improvements** are presented providing actionable steps to facilitate continuous progress and growth of PRISMAP.

This document will be shared with the group of WP8-NA5 including present and future facilities, in order to prepare the extension of the network, involving additional emerging infrastructures. It can serve as a resource for the forthcoming development of **PRISMAP**$^{+}$ and can also serve as a guide offering insights into the PRISMAP access process for future consortium facilities.

1. Introduction

1.1 Standardisation and harmonisation within PRISMAP

PRISMAP strives to create a paradigm shift in the early phase research on radiopharmaceuticals, targeted drugs for cancer, theranostics and personalised medicine. It seeks to **establish a European standard for medical radionuclides** to accelerate the application of novel radionuclides and the development of innovative radiopharmaceuticals, ultimately leading to better healthcare and improving the lives of European citizens.

PRISMAP's main goal is to establish a sustainable source of **high purity grade "novel" radionuclides** for research in nuclear medicine. To this end, PRISMAP brings together a consortium of key and upcoming major European infrastructures to become a **single-entry point** for all researchers active in the nuclear medicine field including SMEs, global pharma companies, nuclear centres, hospitals and universities.

Access to these novel radionuclides and to translational medical research facilities where the radionuclides can be readily used, is directed through a web-based access platform on the PRISMAP public website. The establishment of this platform has been done within the web-access work package WP1-TNA1 and has been fully described in deliverable D1.1, which also includes the descriptions of both the Guide for Applicants and the online User Application Form.

During the course of the project, WP1-TNA1 has strived to further **harmonise and standardise the PRISMAP access process** to ease the use of the services offered and improve the access procedures. This involved reviewing existing access procedures, identifying best practices based on return on experience and implementing them in a common set of access procedures.

1.2 Scope of deliverable D1.2

The overall purpose of this deliverable D1.2 is to provide a harmonised and standardised access process for the PRISMAP services (for both production and biomedical facilities). Access is meant for deliveries of radionuclides to researchers' premises as part of WP2-TNA2 services, while it means experiments performed at or researchers hosted in biomedical institutes of WP3-TNA3. It builds further upon deliverable D1.1 'Web Access Platform'.

This document provides an overview of the steps involved in obtaining access to the PRISMAP services. It also defines additional documents that have been developed in relation to the access process. Furthermore, improvements made to the online access application process and some lessons learned with suggestions for future calls and/or future projects are outlined.

2. PRISMAP access

PRISMAP offers access to:

1. Production and delivery of high-purity grade "novel" radionuclides for medical research (WP2-TNA2).
2. Biomedical research laboratories (WP3TNA3) to
   a. host the applicants to perform the associated research, or
   b. have a selection of preclinical and clinical research techniques performed as a service, taking advantage of the available expertise.

Access to these services is provided through PRISMAP calls for user projects. Individuals, groups, and organisations are invited to submit a project application via the online access platform at any time between the opening of the call and the submission deadline.

In the past two years, these user calls were launched twice a year and were only open for a specific time.

Example of the timeline of a user call (Call No. 4):

- 7 Aug 2023: Call for user projects opened;
- 29 Sept 2023: Deadline proposal submission: single submission process;
- Early Oct 2023: pre-selection based on eligibility and feasibility, and invitation by the User Selection Panel (USP) based on scientific excellence for the interview;
- 13 Nov 2023: hearings of the applicants by the USP (online);
- Second half of Nov 2023: Publication of the final results and information to the applicants;
- Project started within 12 months before April 2025.

In order to support the ongoing research across Europe and beyond, PRISMAP, as an INFRAIA programme, places a strong emphasis on fostering cross-border exchanges and **exclusively** extends **transnational access**.

Information related to PRISMAP user calls are communicated within the PRISMAP Community, PRISMAP User Forum and provided on the PRISMAP website. Registration to the PRISMAP User Forum is free and available to anyone interested in PRISMAP.

As PRISMAP is nearing its end phase of the project, no new call has been announced yet. Since the lead time between project approval and actual start of the project can extend up to 18 months and the projects need to be finalised before the end of the funding period (i.e., April 2025). A targeted call opening is under discussion together with the request of an extension of PRISMAP.

2.1 Access rules

Access rules and conditions have been established and were first published in deliverable D1.1. The rules are formulated by the PRISMAP consortium based on the relevant provision of the European Commission´s Grant Agreement.

The current rules and conditions are shown below:

2.1.1 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 Organisation 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 the European Union or associated country is eligible but 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 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 which are at the charge of the user. The selected users have to provide their authorisation to receive the radionuclides at the activities requested as well as a list of contacts for delivery.

- 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 must be signed stipulating the legal framework of the collaboration based on the conditions summarised in section 2 of the Guide for Applicants.

2.1.2 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.

2.1.3 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 framework of PRISMAP (MRI TUM and CHUV), have ethics departments in place to accompany the users in this endeavour. As part of the access procedure 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.

The latest approved version of the rules and conditions can be found in the Guide for Applicants, available via the online application platform.

2.2 Access process

The flowchart below (Figure 1) illustrates the general process to gain access to PRISMAP services:

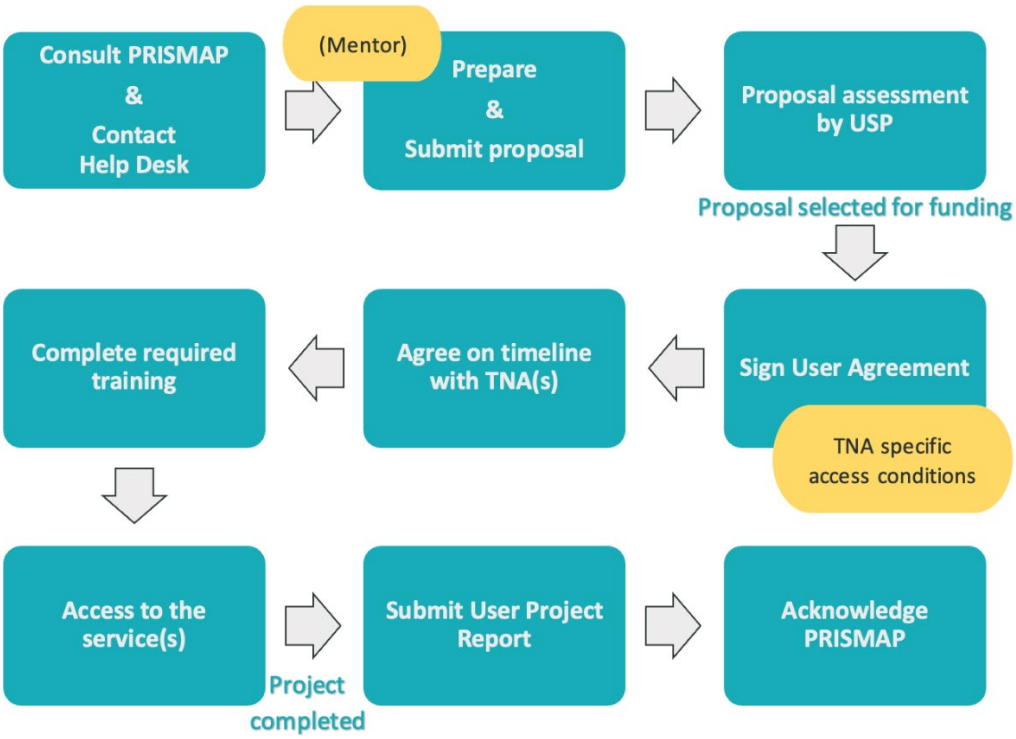

Figure 1. Overview of the steps involved in the PRISMAP access process

1. Consult PRISMAP website & contact Help Desk

Through the PRISMAP website, researchers can discover all available radionuclides and services offered by PRISMAP. The radionuclide portfolio provides an overview of the available radionuclides along the periodic table of the elements. Detailed insights into the production facilities and the biomedical facilities can also be found on the website, offering applicants a comprehensive understanding of the PRISMAP capabilities.

Once a researcher is interested in applying for a project, it is strongly recommended to get in contact with the Help Desk to discuss the project idea. If relevant, a personal PRISMAP mentor will be assigned to assist in the project development.

2. Prepare and submit a project

A Guide for Applicants has been developed to assist applicants in navigating the application process. This guide further specifies the practical information on preparing and submitting a proposal for the PRISMAP user call.

Additionally, a walk-through webinar "How to apply for PRISMAP User Call" has been created and made available on the website to further assist applicants.

Once a call has been opened, applicants can submit their project in the online project application form.

3. Project assessment by User Selection Panel (USP)

Projects are granted on an excellence selection basis and are evaluated based on eligibility, scientific merit, feasibility and logistical requirements through independent peer review by a User Selection Panel (USP).

Selection procedure:

- Peer review by USP: Scientific merit is measured based on part B, section 1-4 of the application form as outlined in the Guide for Applicants. A maximum of five points is attributed to each section.
- Interview by USP: All user projects reaching an overall threshold of 14 out of 20 points are in principle eligible for PRISMAP funding and are invited to hearings.
- Ranking of proposals: Based on hearings, the evaluation of all proposals of a user call are finalised and proposals are ranked and selected for funding.

During the review, the USP will also consider if

- the applicants 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 (in particular transport costs that must be paid by users),
- the applicants are working in countries where radionuclide services are not readily available and verify the transnational access,
- ethical aspects are compliant.

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

- User Selection Panel:

The USP 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 selection criteria and a list of the USP members are available for consultation on the PRISMAP website: Selection procedure.

4. Sign User Agreement

Successful applicants enter into a User Agreement with PRISMAP and the TNA(s) that will provide the services. The specific access conditions for the TNA(s) are communicated to the applicants and are accepted by countersigning the User Agreement. In summary, before on-site access can be granted, the following is usually requested:

- additional facility specific Non-Disclosure Agreement (NDA), contract or user agreement,
- additional documentation that the users need to provide before starting their work,
- site introduction and training: radioprotection, introduction specific labs, waste management rules, etc.

A full description of the User Agreement can be found in chapter 3.

5. Consultations with TNA(s)

In consultation with a TNA representative the timeline of the project will be further defined and agreed upon. In general, this entails the following:

- For radionuclide supply:
  - schedule of availability and delivery dates,
  - transportation of the radionuclide including shipping and containers to be used (note that the transportation is at the charge of the user).
- For access to biomedical facilities:
  - animal ethics, animal use and housing,
  - required on-site training in order to perform the project autonomous and efficient according to TNA safety rules and regulation and to GLP (Good Laboratory Practice) guidelines or even GMP (Good Manufacturing Practice) guidelines as set out in the TNA's specific access conditions.

6. Complete all required training

If specific training has been discussed and agreed upon, the user(s) will have to complete the required on-site training before access is granted.

7. Access to the service

Perform the approved project using the selected PRISMAP services according to the agreed timeline and conform all signed agreements.

8. Completion of the project

At the end of the project, the user must provide a User Project Report to PRISMAP which includes the results obtained and the support provided by PRISMAP.

Details on the User Project Report are further outlined in Chapter 4.

9. Acknowledge PRISMAP

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.

The contents and format of the access process (including related documentation) has evolved over time according to feedback from consortium members, the USP, and the User Forum. Chapter 5 of this document elaborates on the improvements made to the PRISMAP user calls, showcasing the ongoing efforts to optimise the access process.

3. User Agreement

After completion of the project assessment by the USP and before the start of the user project, a User Agreement is signed stipulating the legal framework of the collaboration (see Annex 1).

The document begins by establishing the purpose and scope, defining the parties involved and the overarching collaboration and boundaries of the agreement.

It then provides a duplicate of the access rules from the guide of applicants (see also Chapter 2), followed by more specific conditions addressing key aspects such as intellectual property, liability as well as the financial obligations and payment procedure. Within the specific conditions the date of the (first) radionuclide delivery will be stated and the names and emails of the contact persons at PRISMAP for that specific user project are also specified.

The agreement further stipulates the applicable law and process for settling disputes as well as the period during which the term and conditions outlined in the document are in effect.

The final section consists of the signed consent from both the PRISMAP facility at charge and the main contact of the user group, confirming the acceptance and understanding of the terms. It serves as a confirmation of mutual agreement and compliance.

The agreement includes the following 3 annexes:

- The project proposal as submitted by the applicant via the online platform. It contains the full project as it has been assessed by the USP.
- The invitation letter sent to the applicant after the deliberation by the USP, highlighting the outcome of the project assessment and specific adaptations to the service request.
- The specific access conditions for the PRISMAP facility in charge of the service (compiled in this document under Annex 2).

4. User Project Report

Once the user has received enough services from PRISMAP to finalise the granted project, the user project is considered close to completion. At this point, the PRISMAP technical manager shares the User Project Report template with the main user (Annex 3).

The report includes an initial part to describe all authors and co-authors who participated in the project, including PRISMAP consortium members. The main user is then invited to summarise the context of the project, the main results obtained, including a discussion of these results, and a conclusion to close this part of the report.

The second part collects a description of the PRISMAP services provided during the project, followed by the user's feedback to the PRISMAP consortium. Finally, the user must give the reference of the scientific publication published (or in progress) or of any dissemination activity in progress, past or future, linked to the funded PRISMAP project described.

To remind the user of the dissemination rules as well as the guidelines for acknowledgements (collaborators and funding) for the publication, these are included as an annex to the User Project Report.

The User Project Reports received will form part of the next and final WP1 deliverable "D1.3. User Project" which will summarise all applications, selected projects and their main results.

5. PRISMAP call optimisations

In between the PRISMAP user calls, several refinements to the access process have been implemented, showcasing our ongoing efforts to enhance and streamline the process for a more efficient and user-friendly experience.

- **Guide for Applicants**
  Details on the content of the Guide for Applicants were first described in deliverable D1.1. This guide has been refined and updated between calls, incorporating valuable insights gained from the experiences of the previous call, ensuring a more comprehensive and effective resource for applicants. The latest version of the Guide for Applicants is available for download on the PRISMAP website.
- **FAQ**
  After the first call for projects, a frequently asked questions (FAQ) section has been set-up including commonly asked question to help users to shape their project proposal. This FAQ reflects the interaction between users and the Help Desk. It is accessible through the following link: https://www.prismap.eu/access/faq/.
- **Video: Apply to PRISMAP Call**
  A video explaining how to submit a project has been made available on the online access platform. This short webinar guides applicants through the access process and the online project application form. It is in mainly directed towards PhD students and post-docs for whom it may be the first application into a competitive call. The video is hosted on a SCIPROM YouTube channel: How to submit a project for PRISMAP call 4.

- **Promotion of WP3-TNA3 facilities**
  After the first and second call for projects, it became apparent that there was little demand for WP3-TNA3 facilities in the submitted projects. A dedicated strategy was set up by WP3-TNA3 in collaboration with WP6 and WP7 communication and dissemination to promote the use of the biomedical facilities. For example:
  - Grant for travel and/or accommodation (see next point on travel sponsoring)
  - Actively engage collaborations ➔ mentors (further described below)
  - Continue to update and improve technical details and authorised radionuclides ==> to be published on the website in an easy-to-read table
  - Increase presence on PRISMAP User Forum and social media
  - Furthermore, during the access process, the USP also provides advice to users to take advantage of the availability of a WP3-TNA3 facility close to the production site in order to limit transportation losses of radioactivity.
- **Travel sponsoring**
  Travel, subsistence, and local accommodation costs of users (mainly directed to PhD students) carrying out a project in one of the (bio)medical facilities may be funded by PRISMAP based on daily allowances and country coefficients up to a maximum amount.
- **Mentoring**
  In the third call, several of the submitted proposals were more about getting acquainted to novel radionuclides rather than being innovative. In addition, in some cases, the quality of the submitted documents was not high enough (i.e., specific information was missing) to allow a good selection process. Finally, the return of experience of MRI TUM and DTU showed that it is easier to promote WP3-TNA3 facilities among potential users when they receive mentoring from a PRISMAP consortium member as early as possible in the application process.
  As written in the Description of Action (PRISMAP Grant Agreement Annex 1, Part B), WP3-TNA3 research centres can provide scientific support to future users of PRISMAP to design and organise their in vitro and in vivo experiments in coordination with WP1-TNA1, WP2-TNA2 as well as with the coordinator and the administrative and technical managers.
  Based on these considerations, applicants are encouraged to first contact the Help Desk to present in a few lines their project so that a PRISMAP consortium member could be proposed as a mentor for assistance during the preparation of the project.
  The use of a mentor is not obligatory, but a recommendation that demonstrably increases the chances of success. In Call No. 4, most of the successful user projects were supported by mentors during their preparatory phase (20 projects submitted in Call No. 4, the highest number for one call, with a success rate of 85%, the highest success rate of PRISMAP's four user calls).

6. Lessons learned

- **Access process**
  The main lessons related to the access process have been acted on and have resulted in the amendments of the PRISMAP user calls as outlined in the previous chapter. For example, the technical manager and, in the last calls, the mentors provided significant help with setting the amounts of batches and activities of the radionuclides requested in the user applications. This highlights the need for contacting the help desk and assigning a mentor when needed. Both lessons have been implemented in the access process as presented in chapter 2.
- **User Selection Panel**
  It became clear after the first PRISMAP user call that a pre-screening of the applications was needed before USP meetings to verify that the submitted projects are at all feasible. This task is now part of the WP1-TNA1 manager's responsibilities.
  In the context of this deliverable, a short survey was sent out to the USP members to gather their feedback:

- **Nice opportunity**
  USP members who replied to the enquiry acknowledged the very nice opportunity to be a member of the selection panel. It allowed them to learn a lot from the project proposals and the fruitful discussion with the panel members and consortium members during the project assessments.
- **Selection procedure**
  - The USP members highlighted the fact that the project assessment is challenging as the USP panel represents people with different background, all with their own way of reviewing the projects, nevertheless being subjected to the same scoring procedure. Especially the self-cut-off of 14 points has been found too rigid in respect of a rating of the type "very good" or "good". Some USP members found the scoring fair and efficient while other USP members found it not very transparent. Some members would like to see the opportunity for projects being 'parasitically' possible when production batches are being produced.
  - The USP members were assessing the project without precise knowledge of the availability of the radionuclides and quantities with regards to what the PRISMAP TNAs can provide. It has been suggested that representatives of the requested service facilities should be involved in the selection process. Otherwise, the TNA members should be able to have access to the full proposals received before the selection process committee happens. Indeed, the USP members judged that it was sometimes difficult to balance the panel's assessment of the quality and novelty of the science versus the practicality of being able to supply the material that the applicant has requested. Within the selection procedure the USP proposes to take into account a benefit/cost ratio in terms of PRISMAP resources.
  - When there are a large number of proposals to review, it is difficult for all the reviewers to read and assess all the applications in detail. Some members of the USP have suggested assigning each application to only one part of the panel in order to obtain a better and more detailed review in the case of a large number of applications.

After each call, the USP provides feedback to applicants and assigned project scores are always reported very transparently. However, it has been questioned if publishing the scores actually brings any added value to the researchers. In addition, the assignment of the scores within the USP has been very rigid and has been a topic of debate as outlined in the above USP feedback.

Feedback from PRISMAP facilities

- **Production facilities (WP2-TNA2)**
  - It has not been clearly stated that **delivery dates of the radionuclide** will be decided by the production facility rather than at the request of users, as it is highly dependent on the production cycles of the selected facility. Production should still be cost efficient for the production facility. (Note that this step has now been incorporated in the Access process step 5 'Consultation with TNA(s)' as proposed in Chapter 2, Figure 1.
  - As far as the **quantity of radionuclide** is concerned, there has always been a discrepancy between the production facility and the applicant, because the production facility defines the activity of the radionuclide at a given time after production, whereas the applicant defines it when (s)he starts working with the radionuclide.
  - **Organisation of the transport** of the radionuclide has been a common issue. Most candidates have no idea about prices and transport constraints. Some facilities have developed their own documents to facilitate this task. For example, at PSI, a document has been drawn up for users on what is needed (Annex 4). At ARRONAX, a list of what is needed is provided with the production schedule when the User Agreement is signed. Organising a delivery usually takes between 4 and 6 weeks to obtain all the documents. For countries outside the European Union, additional export authorisations must be requested.
  - It may be useful to give an **estimate or example of the costs** (around €2 per km in France and neighbouring countries - Belgium, Switzerland and Germany - for road transport) and logistical

problems that may be encountered (e.g., customs or authorisation of transport companies that do not cover all countries).
  - The **transnational access condition** is sometimes not compatible with the ALARA principle, which is minimizing the radiological impact and risks "As Low As Reasonably Achievable". In the case of short-lived radionuclides, it can even prevent providing "Access", e.g. delivery, of radionuclides, thus preventing user groups in remote locations to develop their research projects while radionuclides could be made available in a local node of PRISMAP. This would be against the transnational spirit of INFRA projects, i.e. promoting access to services across Europe. We propose in this case that a different mode of – local – access be considered, for instance in a follow-up **PRISMAP**$^{+}$ project.
- **Biomedical facilities (WP3-TNA3)**
  - The wish to have one representative of each WP2-TNA2 and WP3-TNA3 facility involved in the selection process of the user projects. This way, the requested service provider can position itself and give direct feedback on what is feasible and when.
  - With the first user projects it became clear that sometimes the internal administration department of the facility in charge does not accept the PRISMAP documentation related to User Access. This highlighted the fact that existing facilities with fee-for-service experience will have their own access process which also needs to be followed on top of the PRISMAP Access process. (Note that the additional request of documentation or contract has been included in the proposed Access process in Chapter 2)
  - The user should receive information regarding the transport of the radionuclide: for some institutes the transport is arranged by the institute itself and the user only covers the costs by reimbursing the institute after shipping, for others the transport needs to be arrange directly by the user itself. In all cases the institute should provide all necessary information and assistance to the user regarding shipping and the related cost. For example, at ARRONAX, the users can decide themselves which way to proceed as sometimes it is less expensive to use non-French companies.

7. Recommended improvements

In this section, suggested improvements are presented with the aim to further optimise and harmonise the PRISMAP access process.

7.1 Access process

- The **flowchart** outlining the access process (Figure 1) may be made available on the website and included in the Guide for Applicants to provide a quick overview of the various steps in the access process.
- **Access Policy document**: All rules and criteria related to the PRISMAP access could be collected in a single Access Policy document. At the moment these rules are stated in two separate documents (Guide for Applicants and User Agreement), however, they are not necessarily uniform across these two documents due to independent updates of the two documents. As such, having a single document would make harmonisation easier as only one document will have to be controlled. It can then be referred to in the Guide for Applicants and attached to the User Agreement. It is suggested that the access policy document should cover the following topics:
  - Definitions (e.g., "user group", "user group leader")
  - Criteria for application and selection
  - Access arrangements: here it can be stated more clearly that the transportation is at the charge of the user and that the radionuclide delivery schedule and amount will be defined by the production facility in consultation with the user. As suggested in the feedback from the production facilities in the previous chapter, it may be good to give an estimation or example of transportation costs.
  - Application options (see next point of improvement)
  - Dissemination rules
  - Ethics regulations

  - Intellectual property
- The Guide for Applicants and the User Agreement are aimed at users at different stages of the procedure. Those who are not selected for funding, will never use a user agreement. One could therefore also imagine including a user agreement template for information in the guide for application, for information prior to proposal submission. The actual user agreement, however, may differ dependent on the facility in charge.
- **Application options**: Currently there is only one way to get PRISMAP access, i.e., submitting a project proposal for which access is granted based on an 'excellence' selection. It has been suggested that PRISMAP could also allow access for a few "test" deliveries, for example for Nuclear Medicine centres to get acquainted with innovative radionuclides. Having multiple access options would also make it possible to serve several users with one production batch which then becomes cost effective for the production facility. Since some PRISMAP facilities already offer access via multiple schemes to external users, other options could be explored. **Eligibility rule**: The "transnational access" rule for WP2-TNA2 facilities is counterproductive and should be replaced by the "remote access" rule that enables serving users from a geographically closer WP2-TNA2 facility to optimize the overall process.
- **Application form:** Adjust the application form, or make separate ones, to apply for access and secondment to the (bio)medical facilities and/or request services of these facilities. It is not very clear how to fill in the current application form when requesting access to (bio)medical facilities or paid services.
- **User Selection Panel:** The management of the USP should be adapted, depending on the services requested in the user proposal: the coordinators of WP2-TNA2 and WP3-TNA3 should liaise with the requested and involved WP2-TNA2 and WP3-TNA3 facilities early in the selection process. It is suggested that:
  - In case a biomedical facility is requested: The respective WP3-TNA3 representatives must be contacted early by the WP3-TNA3 coordinator.
  - In case a 'first in human' study is requested: The panel should include a person with knowledge of GMP and GCP (Good Clinical Practice).

7.2 User Agreement

The User Agreement would be more comprehensive if it included provisions outlining the conditions for early closure of a project and the conditions for additional deliveries (in order to finalise the granted project). Furthermore, in section 2.2. on ethics regulation it is stated that 'the user must sign a statement that their research complies with ethical requirements', if applicable, this signed ethics statement should be included in the agreement as an additional annex.

7.3 PRISMAP organisation

When exploring the possibility of a PRISMAP follow-up project **PRISMAP**$^{+}$, the following suggestions have been proposed at the Consortium Meeting 6 held in November 2023 in regards to the PRISMAP organisation:

- Generalise TNA2/TNA3 couples with close geographical vicinity for short lived radionuclides (<5h).
- Set up 'radionuclide based'-networks: At-211, Cu-67, Cu-64 for medium lived radionuclides (5h< <3d).

Furthermore, the organisation would benefit from having an overview document with all services and their associated prices. Having a comprehensive understanding of this would be immensely beneficial for discussions pertaining to the sustainability of PRISMAP.

Conclusions

Harmonising access procedures is a complex task, as it encompasses facilities at various developmental stages, ranging from newcomers to those long-established access procedures predating the start of PRISMAP. For that reason, the focus of this deliverable has been on the development of a common PRISMAP access process, which might come on top of established systems at the facilities. Optimising this process is crucial for enhancing efficiency, reducing complexities, and ensuring a more streamlined and accessible user experience.

Four PRISMAP user calls been launched since the beginning of PRISMAP. The access procedure and USP selection criteria were defined at the very beginning of the project. In total, 45 projects were submitted out of which 32 were selected. Over the past two years, several refinements have been made to the access procedure, reflecting PRISMAP's dedication to progress. From the first call to the last one, we greatly improved the administrative steps associated to the access process. For the first selected projects, it took months to get User Agreements signed whereas in the last call, two User Agreement got signed within a few weeks after USP approval.

This deliverable provides a thorough overview of the PRISMAP access process, the lessons learned from the previous calls, the optimisations that have been implemented so far and provides some valuable suggestions for future improvements.

This document can serve as a resource for the forthcoming development of **PRISMAP+** and can also serve as a guide offering insights into the PRISMAP access process for future consortium facilities. It will be shared with WP8-NA5 in order to prepare the extension of the network, involving additional emerging infrastructures.

Finally, the first user projects are close to completion and are currently supported through the final steps of the access process, i.e., submitting the User Project Report and acknowledgement of PRISMAP. All User Project Reports will be collected in the next deliverable D1.3 'User Projects' which will summarise all applications, the selected projects and their main outcomes.

Annex 1 User Agreement

User Agreement

User project identifier:

User project title:

Main contact of the user group:

PRISMAP facility in charge:

1. Purpose and scope

The purpose of this User Agreement is to stipulate the legal framework for the conditions of the PRISMAP services, requested by [Name and short name of the user group], hereafter called User, represented by [Name and affiliation of the main contact of the user group] and supplied by the PRISMAP facility in charge (identified below and hereafter referred to as *PRISMAP*) for the User's project [project name, project number] (the *Project,* as described in Annex 1 and invited for funding in Annex 2), within the framework of the European Union Horizon 2020 PRISMAP project under Grant Agreement no. 101008571, selected and approved by the PRISMAP project User Selection Panel under the general conditions stipulated in Section 2 below.

Facility in charge: [Name of PRISMAP facility in charge, the one last involved in the services].

During the course of a project, it may become necessary to reallocate production or medical application tasks to different PRISMAP facilities to accommodate downtime of certain facilities or to regroup different user requests to make best use of PRISMAP resources. It is therefore not guaranteed that throughout the duration of a user project the requested services will be delivered from the same 'facility in charge' marked above. In the event of a change of 'facility in charge' during a project, users may be asked to sign an addendum to this User Agreement to cover the involvement of this other facility.

2. General conditions

- To foster cross-border exchanges, the European Commission requires that access to PRISMAP services is transnational. Each user group leader and the majority of the individual users accessing the PRISMAP services must work in a country other than the country(ies) where the PRISMAP facility(ies) providing the services is/are located. The European Organisation for Nuclear Research (CERN) and the Joint Research Centre - European Commission (JRC) are international organisations and access is considered transnational from all user countries.
- Access for user groups with a majority of individual users not working in an EU or associated country is limited. Furthermore, in line with measures adopted by the European Union in response to Russia's military aggression against Ukraine (see Council Regulation (EU) No 269/20141, as amended), access is also restricted where it is sought by certain natural or legal persons, entities or bodies listed in Annex I to that Regulation (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02014R0269-20220315&from=EN).
- Each user group's individual 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 *Project* must relate to the use of radionuclides in medical applications. The finality of the *Project* should be to improve the diagnosis or treatment of human disease.
- The requested radionuclides and biomedical application services should be available from at least one of the PRISMAP infrastructures. Expressions of interest for innovative radionuclides that are not yet available from any of the facilities involved in the European Union Horizon 2020 PRISMAP project are also welcome to help guide the project's development and broaden its offer.
- *PRISMAP* shall provide the User with the PRISMAP radionuclide free of charge, as long as the total costs do not exceed the total PRISMAP budget available, and except for the radionuclide packaging and shipping costs. The User has to provide their authorisation to receive the radionuclides for the activities requested.
- *PRISMAP* shall provide the User with free of charge access to its infrastructure, including all the logistical, technological and scientific support, as well as any specific training that is normally provided to external users of its infrastructure and their personnel.
- Medical application services for the User will be reimbursed according to the normal internal rules and procedures of the facility, as long as the total costs do not exceed the total PRISMAP budget available, except for radionuclide packaging and shipping fees.

- Individual users present at a PRISMAP facility should abide by the normal working practices, health and safety regulations, access controls and any other regulations governing conduct or behaviour that are required by that facility and/or its infrastructure.
- *PRISMAP* shall not be liable for, nor made party to, any claim that may arise from the use of any radionuclide it has supplied or medical facility that it has made available. The use of radionuclides and presence of individual users at a PRISMAP facility are at such users' own risk. Neither *PRISMAP* nor any *PRISMAP* personnel accept liability for the damage or loss of any instruments, apparatus and test equipment of the User or their personnel, whether or not such damage or loss was caused directly or indirectly by *PRISMAP* or its personnel's negligence. Individual users will ensure they have appropriate insurance, including personal health, accident cover and personal liability, for their activities.
- All user groups must comply with the ethics and dissemination rules detailed below.

2.1 Dissemination rules

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

For each user group project, a publishable project summary and a publishable summary of the results will be published on the European Union Horizon 2020 PRISMAP project website www.prismap.eu. The publication of results in journals or at conferences is strongly encouraged.

To ensure the long-term sustainability of the PRISMAP initiative, proper recognition of the contributing facilities, their services and the involved persons is necessary. 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.

The user group shall contact the PRISMAP Technical Manager 30 days prior to submission of publications or other communications of results that were obtained by making use of services provided by PRISMAP (radionuclides delivered or medical services provided). The Technical Manager will communicate to the user group the list of PRISMAP facilities and persons that have contributed to each specific project and the way this contribution must be acknowledged in the publication/communication or where co-authorship is required to reflect specific scientific contributions.

Users must comply with Horizon 2020 dissemination rules (i.e. acknowledge that their work was financially supported by the European Union's Horizon 2020 Research and Innovation Programme by including the following acknowledgement: "*This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101008571 (PRISMAP)*"), 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.

2.2 Ethics regulations

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

The User has read and understood PRISMAP's ethics requirements and agrees to conduct the *Project* in accordance with these requirements.

3. Specific conditions

3.1 Delivery of radionuclides

PRISMAP hereby undertakes to use its reasonable efforts to deliver the radionuclides by [Date], always subject to availability of *PRISMAP* resources and compatibility with its scientific programme as well as subject to the resources of any other facility/ies involved. Accordingly, *PRISMAP* reserves the right to reschedule part or all of the delivery at its discretion, taking into account its scientific programme or the availability of its key personnel.

PRISMAP will arrange packaging and shipping of the radionuclides (including all export formalities as applicable), in accordance with applicable regulations. Per 3.5, below, User shall bear all related costs. Title to and risk in the radionuclides shall transfer to User upon their delivery to carrier at loading point.

3.2 Use of radionuclides

User shall use the radionuclides exclusively for the agreed, non-military, purpose set out in this *Project* and shall ensure that its use of the radionuclides complies with all applicable laws and standards, in particular any laws concerning safety, including radiation protection and the transport and handling of dangerous goods, as well as data protection, medical ethics, testing and trials.

3.3 Intellectual Property

Nothing herein shall imply a transfer of any of either party's intellectual property to the other party, and each party will retain exclusive interest in and ownership of its intellectual property developed before the execution of this User Agreement or developed outside the scope of either this *Project* or the PRISMAP project generally.

3.4 Liability

The radionuclides are provided by *PRISMAP* on an as-is basis, without any warranty, express or implied, of any kind including as to quality or fitness for purpose. In particular, User understands and acknowledges that *PRISMAP* has not obtained any approvals or certifications for the radionuclides from any technical, safety or other authority. Any claim of quality of product or certification given by *PRISMAP* will be only given on behalf of that facility, not the PRISMAP consortium as a whole. Regardless of any claim of quality of product or certification, *PRISMAP* nonetheless accepts no liability in respect of the radionuclides or medical application services it provides, and User shall hold *PRISMAP* free and harmless from and indemnify them for any loss, damage or injury (i) resulting from User's use of the radionuclides and/or the medical application services, or (ii) User's breach of applicable laws.

3.5 Payment of Fees

User bears all costs of shipping the radionuclides from *PRISMAP*, including, where applicable, shipping between all other facilities involved in the *Project*. User shall pay the corresponding invoice from *PRISMAP* within 30 days of receipt of the invoice on the stated account.

3.6 Contact persons

Your contact persons at *PRISMAP* will be

- Main contact: [Name], [Email].

- PRISMAP Technical manager: Charlotte Duchemin, Charlotte.Duchemin@cern.ch
- PRISMAP Ethics manager: David Viertl, David.Viertl@chuv.ch

4. Applicable law and settlement of disputes

The law of Belgium shall govern this User Agreement. All disputes arising out of or in connection with this User Agreement, which cannot be solved amicably, shall be finally settled under the WIPO Expedited Arbitration Rules by one arbitrator appointed in accordance with the said Rules. The place of arbitration shall be Brussels if not otherwise agreed by the conflicting Parties. The award of the arbitration will be final and binding upon the Parties.

5. Duration

The *Project* must start at the latest 18 months after selection for funding and must then be completed within the duration of the European Union Horizon 2020 PRISMAP project.

This User Agreement shall expire 5 years from the date last written below. User's obligations in clause 3.3 above shall continue in effect notwithstanding the expiration of this User Agreement.

By countersigning this User Agreement, User confirms, on its and its individual users' behalf, its acceptance of the terms and conditions set out in this User Agreement, including any "Specific Conditions" set out in Annex 3.

Consent of the parties to accede to the User Agreement

[PRISMAP facility in charge]

[Name and role of the signatory]

Place, date

Signature

[Main contact of the user group]

Place, date

Signature

Annex 2 Specific access conditions of the PRISMAP facilities

Option 1: ARRONAX

Use of ARRONAX Research Facilities and Services

In addition to the rules and guidelines as prescribed in the PRISMAP User Agreement the following specific conditions must be met for visiting scientific personnel / users at the GIP ARRONAX premises

Admission

Prior permission is required before access to ARRONAX is granted, ensuring that radiation safety and GMP standards will be respected.
When ordering radionuclides, all information assuring that the right to receive and handle radioactive material is granted by regulatory authorities must be provided in due time. This also applies for information required for a secure and safe transportation to the User labs.

Safety regulations

All local ARRONAX working rules and safety guidelines must be strictly adhered to. Work at the ARRONAX Lab facility may require completion of additional, local training.

Good laboratory practice

GLP (Good Laboratory Practice) guidelines need to be adhered at all times and in some labs GMP (Good Manufactoring Practice) guidelines must be followed.

Option 2: CERN

Use of CERN Research Facilities and Services

The European Organisation for Nuclear Research (CERN) operates a range of unique research facilities for the execution of its scientific programme, for fundamental, non-military purposes only.
As part of its mission, CERN hosts scientists from institutes and universities worldwide, who use these facilities on behalf of their institutes or universities to perform research or contribute to their construction, operation or maintenance. Access to such facilities is subject to the provisions of Memoranda of Understanding (MoU) and Agreements concluded with CERN.
In addition, CERN may decide to grant access to its research facilities to researchers from other entities, including from the private sector, for instance in the framework of its Knowledge Transfer projects, its Medical Applications Programme, as well as European Union and similar grant schemes, to perform their own research for defined periods of time. Such access is subject to the following terms and conditions, without prejudice to the provisions of any MoU or Agreement concluded between CERN and the User requesting access:

Admission

Admission of a User to a CERN research facility is subject to fulfilment of applicable criteria and completion of the procedures established by the host research facility.
Each individual researcher sent by the User shall complete the relevant CERN registration form for access to the CERN site. The researchers shall not be granted personnel status at CERN.

Use

Use of the research facility shall be exclusively for the agreed, non-military, purpose. CERN will give priority to the use of the research facility for the execution of its own scientific programme.
The research facility is made available on an “as is” basis, without any express or implied warranty, including as to the fitness of the research facility for the agreed research or the quality of any results.
Use of the research facility may be subject to payment of a fee, payable by the User upon issuance of an invoice by CERN. User shall comply, and ensure compliance by its researchers, with applicable laws as defined in Section 1.1 of the CERN document entitled “Working on the CERN Site”[1], including in matters of safety, work and residence permits as well as social insurance, and with the provisions of Sections 2 to 5 of this User Agreement. User shall further ensure compliance by its researchers with any instructions given to it or to them by the research facility coordinator.

Medical Insurance

User shall ensure that its researchers, including any accompanying family members, have medical insurance cover that is adequate in CERN’s Host States, Switzerland and France. Such insurance shall include cover for occupational illness and accidents for the researchers for the duration of their presence at CERN.

1 https://edms.cern.ch/ui/file/1155899/LAST_RELEASED/*.pdf. The term “contractor” shall be read as referring to the Party.

Option 3: CHUV

Use of CHUV Research Facilities and Services

The Lausanne University Hospital (Centre Hospitalier Universitaire Vaudois – CHUV) is a university medical centre recognised for its clinical and academic excellence and a privileged place of training for all health professionals and other professions linked to the hospital's activity.

The CHUV-AGORA Cancer Research Center is at the heart of the academic institutions of the Lemanic region and brings in the same building fundamental research and clinical research to fight against cancer. The CHUV-AGORA biomedical facility with its unique technical resources and expertise can offer to the PRISMAP users:

- Evaluation of new radiopharmaceuticals
- In vitro and in vivo characterisation of novel radiopharmaceuticals
- PET/SPECT/CT/MRI imaging in small animal models
- Clinical trial (first-in-human)

Admission

To conduct their research, the PRISMAP Users will have access at the premises of CHUV pursuant to the terms of this Agreement and, among other things, to hot cells, microPET/SPECT/CT, dedicated animal facility for radioactive mice, GMP radiopharmacy and fully equipped radiopharmacy laboratory. CHUV-AGORA agrees to make its facilities available to the PRISMAP Users for testing, evaluation and enhancement at the CHUV premises, subject to the specific terms and conditions hereinafter specified, in addition to the terms and conditions of the PRISMAP User Agreement:

Confidentiality

The PRISMAP Users hereby undertake to keep confidential all information, research results and/or details of technical realisations (hereafter "the Information"), whether tangible or intangible, oral, visual, written or electronic, or in any other form, to which the PRISMAP Users gain access during visits to the CHUV's facilities. They further undertake not to divulge the Information, directly or indirectly, to third parties and the Information shall under no circumstance be the subject of a patent application or any other intellectual property protection by the PRISMAP Users, nor used for other non-for-profit purposes outside the scope of the PRISMAP Project.

The PRISMAP Users recognise that CHUV has received and in the future will receive from third parties their Confidential Information subject to a duty on CHUV's part to maintain the confidentiality of such information and to use it only for certain limited purposes and not specifically for the PRISMAP Project. PRISMAP Users agree that they owe CHUV and such third parties during the term of this Agreement and thereafter a duty to hold all such Confidential Information in the strictest confidence, and not to disclose it to any person, firm, or corporation or to use it for any purposes on pain of penal action.

Data protection

The PRISMAP Users undertake and warrant that, if in the course of this PRISMAP Project, they should have access to patient data, they will process any and all Data including but not limited to patients' data received

from or made available by CHUV or derived from such data or to which they have inadvertently become aware:

(i) solely on behalf and solely for the purposes of the PRISMAP User project or as otherwise expressly provided for by the CHUV;

(ii) in accordance with the instructions of the CHUV (which may be given by any means, including e-mail).

The PRISMAP Users undertake, prior to any processing, appropriate technical and organisational measures as defined by the DPA to protect the Data from unauthorised processing, including any processing not expressly authorised by this Agreement and including accidental loss or destruction of, or damage to, such Data. The PRISMAP Users shall comply with such practices and procedures as are required by CHUV and generally act in accordance with guidelines and regulation applicable at CHUV.

Compliance, warranty, liability

Compliance

The PRISMAP Users shall carry out the Agreement in accordance with:

- Good scientific practice[2];
- Good Clinical Practice (GCP);
- any applicable direction received from a Regulatory Authority or ethics committee with jurisdiction over the Agreement;
- any applicable laws (namely the Federal Act on Data Protection and its ordinance), rules, regulations, practices, operating procedures, codes, and guidelines, including but not limited to, legislation appropriate to clinical Studies, medical treatment, and the processing of personal and medical data; and
- the provisions of this Agreement and its annexes.

No Warranties

CHUV makes no warranties, either express or implied, including but not limited to warranties of originality, merchantability and fitness for a particular purpose of the Services and of the Results. CHUV shall keep CHUV's facilities in a condition in compliance with the applicable law, proper execution of this Agreement and performance of the Services. However, PRISMAP Users acknowledge and agree that the equipment and CHUV's facilities are provided for PRISMAP Users' use "as is, where is" without warranty of any type or kind, including any warranty that either is merchantable or fit for PRISMAP Users' intended use or for any other particular purpose. PRISMAP Users assume the entire risk that any equipment, or CHUV facility, does not satisfy PRISMAP Users' needs or expectations in any respect, regardless of whether any defect or deficiency is caused in whole or in part by PRISMAP Users' negligence or other fault.

Liability

PRISMAP Users shall use CHUV's facilities only in the scope of this Agreement. PRISMAP Users shall at all times (i) observe all CHUV's rules and regulations while on CHUV's premises, including but not limited to rules and regulations designed to protect the safety of persons and property, and (ii) follow the directions and instructions of CHUV's personnel with respect to the PRISMAP Users' use of the equipment and the facilities, and otherwise with respect to PRISMAP Users' activities while on CHUV's premises. PRISMAP Users shall immediately reimburse CHUV for the full cost of repair or replacement of any equipment, or any other CHUV's property, which is damaged, destroyed or stolen by PRISMAP Users or its staff. PRISMAP Users shall use its reasonable judgment in determining whether damaged equipment or other property should be repaired or replaced. To this end, PRISMAP Users agree to maintain an adequate insurance coverage.

[2] https://www.unil.ch/files/live/sites/central/files/textes-leg/4-rech/dir4-2-integrite-scientifique4.pdf

Option 4: DTU/ Hevesy Laboratory

Use of DTU Research Facilities and Services

Hevesy Lab is the primary DTU facility involved in PRISMAP. DTU is "Denmark Technical University" and has a shared commitment to developing and creating value and using the natural and technical sciences to benefit society. DTU is involved in education, research, scientific advice, and innovation on a daily basis and in keeping with the three fundamental values: credibility, innovative thinking, and commitment.

In addition to the rules and guidelines as prescribed in the PRISMAP User Agreement the following specific Hevesy conditions must be met for visiting scientific personnel / users at the Hevesy Laboratory premises:

Admission

Prior permission is required before access to the Hevesy Laboratory is granted, ensuring that radiation safety and GMP standards will be respected.

Safety regulations

All local Hevesy Lab working rules and safety guidelines must be strictly adhered to. Work at the Hevesy Lab facility of DTU may require completion of additional, local training.

Good laboratory practice

- GLP (Good Laboratory Practice) guidelines need to be adhered at all times.
- DTU Code of Conduct for Research Integrity[3] needs to be adhered at all times.

[3] https://www.inside.dtu.dk/

Option 5: JRC

Use of JRC-Karlsruhe Research Facilities and Services

In addition to the rules and guidelines as prescribed in the PRISMAP User Agreement the following specific conditions must be met for visiting scientific personnel / users at the JRC-Karlsruhe premises

Admission

Prior permission is required before access to JRC-Karlsruhe is granted, ensuring that security and radiation safety standards will be respected.

When ordering radionuclides, all information assuring that the right to receive and handle radioactive material is granted by regulatory authorities must be provided in due time. This also applies for information required for a secure and safe transportation to the User labs.

Safety regulations

All local JRC-Karlsruhe working rules and safety guidelines must be strictly adhered to. Work at the JRC-Karlsruhe Lab facility may require completion of additional, local training.

Option 6: NCBJ

Use of NCBJ Research Facilities and Services

In addition to the rules and guidelines as prescribed in the PRISMAP User Agreement, the following specific conditions must be met for visiting scientific personnel / users at the NCBJ Radioisotope Centre POLATOM:

Admission

Prior permission is required before access to NCBJ Radioisotope Centre POLATOM is granted, ensuring that radiation safety standards will be respected. Access to the GMP certified manufacturing laboratories will not be provided.

When ordering radionuclides, all information assuring that the right to receive and handle radioactive material is granted by regulatory authorities must be provided in due time. This also applies for information required for a secure and safe transportation to the User labs.

Safety regulations

All local NCBJ Radioisotope Centre POLATOM working rules and safety guidelines must be strictly adhered to. Work at the NCBJ Radioisotope Centre POLATOM Lab facility may require completion of additional, local training.

Good laboratory practice

GLP (Good Laboratory Practice) guidelines need to be adhered at all times and in some labs GMP (Good Manufactoring Practice) guidelines must be followed. Any experiments involving the use of animals can be planned only after the permission of the local ethics committee.

Option 7: PSI

Use of PSI Research Facilities and Services

Safety regulations

You acknowledge that the radionuclides required for your experiment will be shipped to you and you will not spend time utilizing the facility's laboratories, due to the stringent safety conditions.

True information

All specifications made during the proposal submission or later must be certainly true to the best of your knowledge. The samples that will be investigated during the experiment must correspond to sample declarations in the proposal. Any deviation must be declared to the local contact (Zeynep Talip and Nick van der Meulen) and the facility management well ahead of the experiment.

Good scientific practice

You need to respect the PSI guidelines for research integrity and good scientific practice.[4]

Data policy

PSI has defined a data policy[5] for research data according to the principles of "transparency" and "open data". It pertains to the ownership of, the curation of and access to experimental data and metadata collected and/or stored by PSI research infrastructure. Acceptance of this policy is one condition for the award of access to the PSI research infrastructures.

Publication policy

There are certain requirements that must be fulfilled by publications based on experiments at the different user facilities of PSI. In this case, a separate collaboration agreement must be signed between PSI and the User (or Non-Disclosure Agreement) pertaining to the experiment and publication of the data.

[4] https://www.psi.ch/sites/default/files/import/integrity/DokumenteDE/Integritaet%2520in%2520der%2520Forschung_PSI_2014_2.pdf

[5] https://www.psi.ch/de/science/psi-data-policy

Option 8 : SCK CEN

Use of SCK CEN NURA research facilities and services

SCK CEN may decide to grant access to its research facilities to researchers from other entities, including from the private sector, for instance in the framework of its NURA Program, as well as European Union and similar grant schemes, to perform their own research for defined periods of time.

In addition to the rules and guidelines as prescribed in the PRISMAP User Agreement the following specific SCK CEN access conditions must be met by the User and by all researchers sent by the User.

Access

Each individual researcher sent by the User shall complete the relevant SCK CEN registration form for access to the SCK CEN site. Further information can be found on the SCK CEN website: External contractors at SCK CEN[6]

In order to be authorised to perform work on the SCK CEN site, the User's researchers are required to be appropriately informed of the applicable safety regulations and the site rules and regulations[7]. User shall further ensure compliance by its researchers with any instructions given to it or to them by SCK CEN and the research facility coordinator.

Use of NURA research facility

Use of the NURA research facility shall be exclusively for the a priori agreed, non-military, purpose. SCK CEN will give priority to the use of the research facility for the execution of its own scientific programme.

The NURA research facility is made available on an "as is" basis, without any express or implied warranty, including as to the fitness of the research facility for the agreed research or the quality of any results.

The User shall complete a *NURA research facility Access request* form in order to receive permission to access the NURA research facility, this includes receiving an SCK CEN ALARA approval. Additional ethics approval by the SCK CEN Animal Ethics Committee might also be needed.

Depending on the nature of the project and the outcome of the *NURA research facility Access request* a separate collaboration agreement might have to be signed between SCK CEN and the User pertaining to the experiment and publication of the data.

[6] https://www.sckcen.be/en/visiting-sck-cen#anchor-external-contractors-at-sck-cen

[7] https://www.sckcen.be/sites/default/files/uploads/Praktisch-Contact/EN/1_Site_Regulations_for_Contractors_at_SCKCEN.pdf The term "contractor shall be read as referring to the User.

Option 9: MRI TUM

Copy for the user
Copy for the HR department
Copy for the clinic / department

Klinikum rechts der Isar

Technische Universität München

User agreement

Between

Klinikum rechts der Isar
Ismaninger Str. 22, 81675 Munich, Germany
represented by its board of directors
-Klinikum-,

and

Mr. / Mrs., DOB
residing in:
Citizenship -German-
-User-

§ 1

In the time **from … to …**, the user is permitted to stay in and gratuitously use the equipment of the Department of …**, Director: …..,** at Klinikum rechts der Isar of the Technical University of Munich.

The purpose of this agreement shall be research within the scope of the Horizon 2020 PRISMAP project of the European Union under the grant agreement No. 101008571. In addition to the rules and guidelines as prescribed in the PRISMAP User Agreement, the specific conditions set out in this agreement must be met by users at Klinikum rechts der Isar.

This agreement does not constitute an employment or service contract with Klinikum rechts der Isar or the Free State of Bavaria or the department chair. The agreement is conducted voluntarily on both sides. By signing this document, the user agrees that he/she pursues a salaried employment at another employer, an occupation at a scientific institution or an occupation as an independent physician or self-employed scientist. During his/her stay, the user is assigned to [user group – academic/non-academic research institution, research hospital, research department] from an organisational point of view.

This agreement does not constitute an obligation to service or work performance on behalf of the user. Consequently, the user neither has a work relationship nor a relationship as a quasi-employee with the Klinikum. The user is not a vicarious agent of the Klinikum. A renumeration or other employer contribution is not granted by the Klinikum. Furthermore, this user agreement does not constitute the right to a later employment.

§ 2

The user is subject to the supervision and instruction of the head of the department set out in § 1. The daily operating times are to be adjusted to the usual customs at Klinikum rechts der Isar.

Constraints of the usual operational process caused by the user are to be precluded by adhering to the house regulations and comparable operational provisions. Moreover, the user must take care of

the furniture and equipment and prevent damages. In case of infringements, this user agreement can be terminated with immediate effect.

The parties agree that **medical or dental practice, i.e. the diagnostic or therapeutic treatment of patients shall be non-admissible.**

§ 3

The user is informed about the fact that he/she is not covered by insurance during his/her stay at Klinikum rechts der Isar. The user ensures that he/she has taken out adequate insurance for his/her activities, including a personal health, accident and liability insurance.

Neither the Klinikum, nor the Free State of Bavaria assume liability for items brought in by the user in case their destruction or damage has not been caused by gross negligence or malice.

Both parties agree that the costs of damages that were culpably caused by the user must be borne by him/her. This shall be applicable in case Klinikum could legitimately claim recourse in accordance with the principles of employee liability developed by pertinent jurisdiction from its own personnel when it behaves in the same way.

As the user is neither employed nor quasi-employed, he/she is informed that Klinikum will not cover any contributions towards social insurance. The user must take out adequate insurance coverage by himself/herself.

§ 4

This agreement can be terminated with immediate effect at any time. There is no requirement for a substantial reason. There are no claims for compensation arising from an – also premature – termination of the agreement.

§ 5

The user agrees to strict non-disclosure of any processes that he/she becomes aware of during the term of the agreement. Information must not be provided to third parties. This is also applicable after the end of the term of the agreement.

In case the user is utilizing an own device for the analysis of clinical data, the provisions for patient data protection must be complied with. In particular, patient names must not be used in clear text, but only in anonymized or pseudo-anonymized form. Copying imaging data obtained from preclinical examinations to own digital devices (computers, USB sticks, USB drives etc.) or transferring them via the network to external servers is non-admissible. Exceptions require a dedicated written agreement.

§ 6

The user grants Klinikum an unlimited and exclusive right of use of copyrighted materials, in case these were created due to the research covered by this agreement. Scientific publication of contents suitable for dissemination is explicitly admissible. The dissemination rules set out in section 2.1 of the PRISMAP User Agreement are applicable to any such dissemination, and in addition, the head of department named under § 1 is to be informed in writing before publication.

§ 7

Changes and additions to this agreement are only effective if they are agreed upon in written form.

Copy for the user
Copy for the HR department
Copy for the clinic / department

Klinikum rechts der Isar

Technische Universität München

Munich,

Klinikum rechts der Isar
Technical University of Munich
Commercial Management

…….
Thorsten Martineau
Deputy of the Department of Human Resources

……
Name of user

Annex 3 User Project Report

User project report

...

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101008571 (PRISMAP). This document reflects only the view of the author(s). The Agency is not responsible for any use that may be made of the information it contains.

1. **Authors**
2. **Context of the project (800 characters max. including spaces)**
3. **Results and discussion (1000 characters max. including spaces)**
4. **Conclusions (800 characters max. including spaces)**

Figure 1. An example of a figure including a caption

Table 1 is an example for a table (if necessary).

Table 1. Example table

Column 1	Column 2	Column 3	Column 4	Column 5

1. **Involvement of the PRISMAP services (600 characters max. including spaces)**
2. **Feedback to PRISMAP (600 characters max. including spaces)**
3. **Publications and other dissemination activities (conferences etc.)**

Appendix 1. Dissemination guidelines for user projects as agreed in the signed User Agreement

Dissemination rules

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

For each user group project, a publishable project summary and a publishable summary of the results will be published on the European Union's Horizon 2020 PRISMAP project website www.prismap.eu. The publication of results in journals or at conferences is strongly encouraged.

To ensure the long-term sustainability of the PRISMAP initiative, proper recognition of the contributing facilities, their services and the involved persons is necessary. 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.

The user group shall contact the PRISMAP Technical Manager 30 days prior to submission of publications or other communications of results that were obtained by making use of services provided by PRISMAP (radionuclides delivered or medical services provided). The Technical Manager will communicate to the user group the list of PRISMAP facilities and persons that have contributed to each specific project and the way this contribution must be acknowledged in the publication/communication or where co-authorship is required to reflect specific scientific contributions.

Users must comply with Horizon 2020 dissemination rules (i.e. acknowledge that their work was financially supported by the European Union's Horizon 2020 Research and Innovation Programme by including the following acknowledgement: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101008571 (PRISMAP)"), 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.

Acknowledgements

The list of name(s) to be mentioned in the acknowledgment section is sent to the technical manager by the main contact of the involved facilities.

A general sentence will be added by the corresponding author of the article (user side):

"The authors would like to thank the members of the PRISMAP consortium and of the PRISMAP user selection panel, coordination and management team for their advice and support."

Funding acknowledgement

"This work was supported by the European Union's Horizon 2020 research and innovation programme as a user project of PRISMAP – The European medical radionuclides programme (GA 101008571)".

Annex 4 PSI PRISMAP User Information

Transport of radioactive source

Users are responsible for arranging the transport from PSI to their facility and covering the costs for it.
Note that foreign carriers must be licensed to transport activity on Swiss territory, or partner with a local company.
PSI suggests the following Swiss companies which can also provide delivery to abroad:

- SAR Transporte AG, 5200 Brugg, www.sar.ch, info@sar.ch (ground and airfreight)
- Gerhard Wegmüller GmbH, 8058 Zürich, www.wegi.ch, info@wegi.ch (only airfreight)

The source will be shipped as dangerous goods class 7
UN2915, parcel **Type A**, packing category **II-YELLOW**

Parcel dimensions and weight: 25×16×16 cm, 2 kg, certified according to SDR (741.621) and RSD (SR 742.401.6), certificate **CH/EGI-4'204'142/1** issued 21.12.2005 by SVTI ASIT

Collection address: Paul Scherrer Institute, Building OIPA, Forschungsstrasse 111, 5232 Villigen PSI, Switzerland.
Contact person Dr Pascal Grundler pascal.grundler@psi.ch +41 56 310 2196

PSI is licensed by the Swiss authorities to distribute and export radioactive sources. If needed, a copy of PSI's license can be provided upon request.

Conversely, **PSI needs a copy of the user's license to handle the requested radionuclide**.
Please send your license for handling of Tb-161 to Dr Pascal Grundler (pascal.grundler@psi.ch).
Please highlight the relevant section of the license where the allowed maximal activity is stated for the location where the work will be performed.

To prepare the parcel and the relevant shipping documents, please provide the following information to Dr. Pascal Grundler pascal.grundler@psi.ch:

Complete and exact delivery address
Address for pro-forma invoice/customs if different from delivery address
Responsible person (name and e-mail)
If different from the responsible person:
Person to handle the actual reception of the shipment (name and e-mail, phone)
Responsible radioprotection officer (name and e-mail)

The users are responsible for organizing the documents required by their country for importation and providing them to the carrier in a timely manner.

Tb-161 – Quality control

On the day of transport, PSI will provide the following information to the user:

The type of container:

- < 400 uL Eppendorf vial (screw cap)
- > 400 uL glass vial

and consequently, the volume of the solution.

QC results:

- Labelling yield using DOTATOC (MBq/nmol)
- Specific activity (GBq/mL)
- Radionuclidic purity