

## FEEDBACK FROM PRISMAP

MEDICIS Board

Thierry Stora, CERN 06 Dec 2023

## 6<sup>th</sup> Consortium meeting last week at CTN-medical faculty - Lisbon





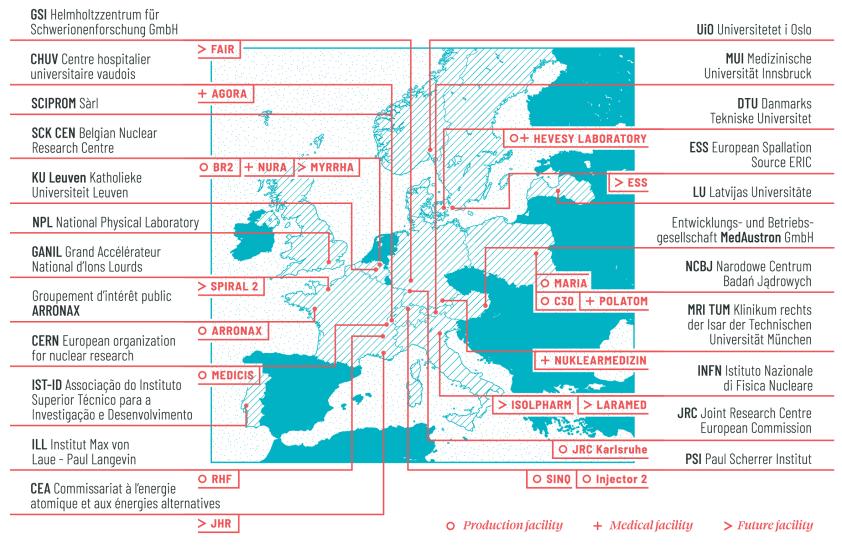








## PRISMAP Consortium: a mix of production sites, biomedical institutes and "support" institutes

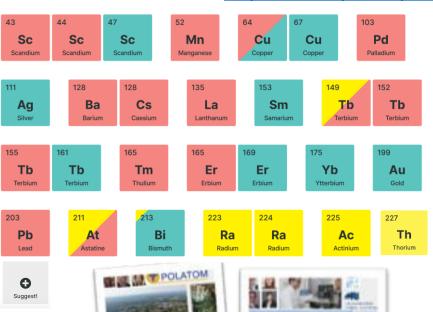




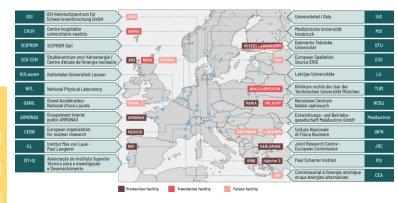


# The European medical radionuclides programme in a nutshell (PRISMAP.EU: Infra project from H2020)

The web interface : https://www.prismap.eu/radionuclides/portfolio/



Parameter	Specification
Half-life	4.04 h
Daughter	Stable Ca-44
Branching Ratio/Decay	94.3% β <sup>+</sup> , 5.7% EC
Production	Ca-44(p,n)Sc-44 [or Ca-44(d,2n)Sc-44 at ARRONAX]
Purification	1 or 2 steps column separation
Chemical Form	In 0.05 M HCI, 0.1 M HCI, 4.85 M NaCI/0.13 M HCI or 1 M NaOAc
Specific Activity	2 GBq/mg
Radionuclidic Purity	99.8% (0.2% Sc-44m)
Radiochemical Purity	Labelling up to 25 MBq/nmol DOTANOC or DOTATATE
Identification	1157 keV gamma line present
Appearance	Clear and colourless solution
рН	Depends on chemical form
Activity available	Up to 1 GBq
Availability	On demand
Grade	Research grade or preclinical grade, n.c.a.

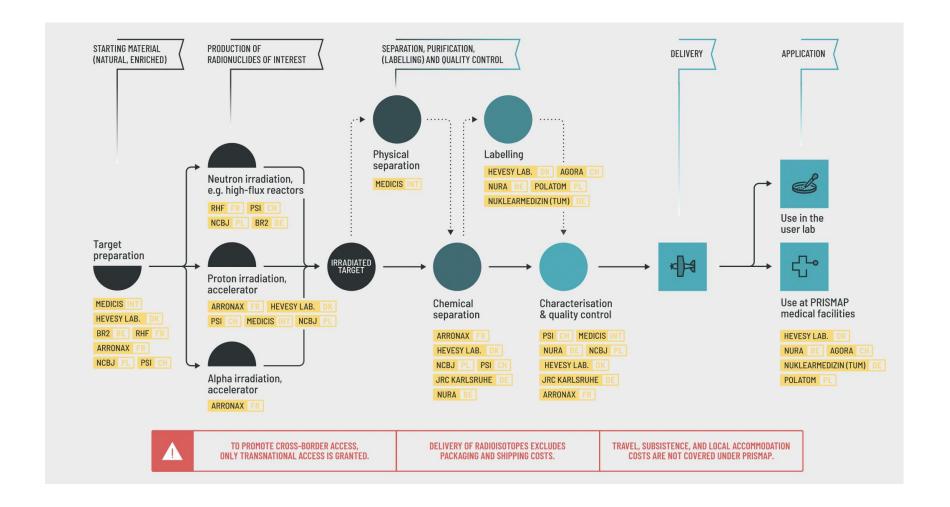








# Organisation of the radionuclide production and users in the consortium







## User projects and services: Call for projects every 6 months, likely only targeted calls for next 18 months

In vivo cellular & molecular imaging lab (ICMI)

**VU Brussels** 

Imaging and Pathology

KU Leuven

Molecular Imaging Center

Antwerp

Pharmaceutical Radiochemistry

TU Munich

Radiopharmaceutical Cancer Research

Dresden (/CZ)

La Tronche

UGA - Inserm

Radiopharmacy

Bordeaux

CEMHTI Radiochemistry Radiochemistry

Orleans

Inserm

Montpellier (/PT)

Fondazione IRCCS Istituto Nazionale dei Tumori

Milano

Dep Molecular Biotechnology Health Sciences,

Torino

Radiochemistry unit,

Hospital Gregorio Marañón

Madrid

Biomedical Engineering and Imaging Science

London

UK

BELGIUM

**USA** 

ARRONAX

MEDICIS

**ES** 

CZECH Rep.

**GERMANY** 

**FRANCE** 

Hopital Frederic Joliot

Orsay

**PORTUGAL** 

**ITALY** 

https://www.prismap.eu/access/user-projects/

SE

PL

**SPAIN** 

#### First publication from a granted project:

Title: Preclinical Evaluation of GRPR Antagonists Labeled with Terbium-161 and Lutetium-177: a Comparative Study Dr. Guenther et al, J Nucl Med /2023/266233

After call 4:

AU

NUKLEARMEDIZIN

POLATOM

x2 projects  $(16 \rightarrow 33)$  1  $\rightarrow$ US

+50% countries (8 →12 UK/CH)

Southern & Eastern (\*) EC country

 $(W \rightarrow W,S,E+Sweden most N)$ 

35(\*) research teams

	Call #1	Call #2	Call #3	Call #4
submitted projects	12	8	5	20
Success rate	75%	75%	20%	85%





#### PRISMAP projects are streamlined through MED-32 PRISMAP





Project proposal to the MEDICIS Collaboration board

## PRISMAP – The European medical radionuclide <u>programme</u>: CERN-MEDICIS contribution

Year	Mode of operation	Radionuclides	Activity collected (total – in MBq)	Max. coll. efficiency (%)	#batch delivered
2022	CERN PSB External sources	Ra-225/Ac-225, Hg-195/Hg-197, Tm-165/Tm-167, Tb-155, <b>Sm-</b> <b>153</b> , Ba/Cs-128, Sc-47, Sc-44	840	5.9	11
2023	CERN PSB External sources	Ra-225/Ac-225, Ra-224, Er-169, Tm-165/Tm-167, Tb-155, Sm- 153, Cs-129, Ba/Cs-128, Sc-47, Sc-44	Last Er-169 ongoing 4 GBq ?	40.0	25 (including 169Er)

In bold: parts contribute to PRISMAP projects as deliveries or developments (WP2, WP9, WP10, WP12).





## The project goes beyond services "only" offered in prismap.eu

Our web interface : <a href="https://www.prismap.eu/">https://www.prismap.eu/</a>



helpdesk@prismap.eu

#### Our biomedical facilities:

https://www.prismap.eu/radionuclides/medical-facilities/









NURA

Studiecentrum voor Kernenergie / Centre d'étude de l'énergie nucleaire — SCK CEN



Nuklearmedizin

Technischen Universität

München - TUM

Klinikum rechts der Isar der

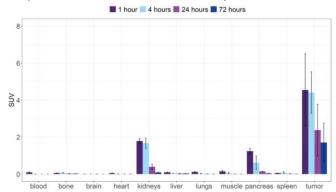
POLATOM

Narodowe Centrum Badań Jądrowych – NCBJ



#### Standardized radionuclides specifications, intercomparison, new data











### MEDICIS Impact on Shipping across EU (and beyond)

#### PRISMAP Shipping Highlights: Transport by dedicated flight

From CERN to DTU Tm-165 Half-Life 1.25 day



- Expected departure on Friday 20/11 at 09:00

- Expected delivery on Monday 23/11 at 14:00 Delivery on D+3.2  $\rightarrow$  83 % loss of activity

Price : **2984 €** 

→ Dedicated flight

Transporter: World Infinity Services

- Departure from CERN on Friday 20/11 at 11:05 - Arrival at DTU on Friday 20/11 at 15:30

Transport time from CERN to DTU: 4h25min

Price: **15432** € (ex. VAT)

Transport time divided by 17.4

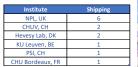








#### Shipping CERN- PRISMAP



	RN	Shipping	
P	Ac-225	3	
Т	m-167	2	Ì
P	\g-103	1	l
Е	la-128	1	l
(	id-149	1	l
Т	b-152	1	l
Т	b-155	1	l
F	la-224	1	J
Т	m-165	1	ļ
F	la-225	1	l







Price multiplied by 5.2

This also creates difficulties: needs to provide framework for deliveries outside of MEDICIS partners



PRISMAP CM6 2023

T. Stora, CERN – CM6– Nov 2023

### "Key Performance Indicators" (do not mix up with those started for MEDICIS)

- to provide at least 10 emerging radionuclides at Day 1 : 16 to be delivered
- four calls for projects per year will be organised, and the radionuclide production and their medical translation scheduled
  - So far , 2x/year seems to be more appropriate need to keep up until 04-2025 (or extended)
- The access provided to at least 20 research teams across Europe. Fund 50 user projects for radionuclide production (25 for biomedical research): 23 projects
- centralised through the platform and the USP, and the capacity of the consortium to react to the requests will be managed by the Coordination Team
  - 4 additional radionuclides offered;
- radionuclides from PRISMAP consortium will be supported for use in early-stage research programmes. For more advanced research, supply from PRISMAP should also be supported by specific research grants or industrial financial schemes obtained by the research groups
  - Interactions with EFPIA/ Industry started



10 CERN

### PRISMAP objectives

- Provide access to new radionuclides and new purity grades for medical research
- Create a common entry port and web interface for the starting research community
- Enhance clarity and regulatory procedures to promote research with radiopharmaceuticals
- Unlock the biomedical research through better data on radionuclides
- Ensure the long-term sustainability of PRISMAP

All are ongoing!!





#### Our future

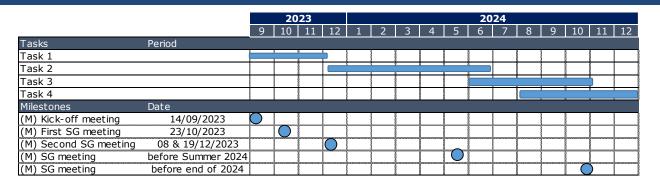
- Mike Lamont invited by the EC to participate in high level round table early this year with Commissioner Marya Gabriel:
- PRISMAP brings together key European, national and regional isotope production infrastructures, of important research infrastructures in large laboratories
  - A sustainable source of high purity novel radionuclides for medical research targeting the development of a new generation of radioisotopes for medicine.
  - A single entry point for the pioneering research community using standardised access procedures.
- There is a relatively short product lifecycle of around a decade for diagnostic, therapeutic and indeed "theranostic" treatments
- Means of upscaling the production of these novel radionuclides are being explored, in the form of innovative production technology, new purification methods, new data and proof-of-concept investigations to facilitate the development of new treatments from test bench to patient care
- CERN-MEDICIS facility, takes advantage of the proton beam delivered to ISOLDE to irradiate targets-also received from external institutes - for non-conventional radionuclides to be extracted from the targets by mass separation
- It is a long game and a long-term commitment; support will be required to reach the appropriate level of integration and maintain it for the evolving needs of the community and help it unlock the potential of this fast-evolving research area.





### Our future: "European Radioisotope Valley Initiative" plan from EC

#### **ERVI Feasibility study indicative schedule & SG involvement**



ERVI SG will be deeply involved in the study, first in Task 1. SG consultations for the next phases will be defined later.

#### Short-term / Task1

#### Brain-storming sessions

The project team is conducting individual brain-storming sessions to define the tentative sets of scenarios + projects + alternatives + EU intervention options. Several SG members have already been solicited. If other members are interested, please volunteer.

4/12/2023: Transmission to ERVI SG of the 6 preliminary sets of scenarios/projects/alternatives/EU intervention options for further screening and <u>discussion on 8/12/2023</u> (face-to-face in Luxembourg)

19/12/2023 (TBC): Finalisation with ERVI SG of the 6 retained scenarios/projects/alternatives (or combination thereof)



ERVI Feasibility study – Methodology ERVI Steering Group – 23/10/2023





# PRISMAP White paper under elaboration: Towards PRISMAP-Plus (PRISMAP+)

A few striking points :

MEDICIS is the 1<sup>st</sup> mass separation facility dedicated to biomedical research (implications on organisation and mode of operation, safety, programme, traceability, QA, etc) worldwide

Europe is the only region where a network of redundant mass separation facilities for biomedical research is foreseen to shape in the next 2 years (SPES, ISOL@Myrrha hot separator) and 7 years (ISOL@Myrrha online, TATOO@PSI, SMILE @ Nantes, possible option in Romania)















This project has received funding from the European Union's Horizon 2020 researce and innovation programme under grant agreement No 101008571 (PRISMAP).