SECURE

Strengthening the European Chain of sUpply for next generation medical RadionuclidEs

THE SECURE PROJECT

A brief overview of the project - outline and highlights

Govert de With - NRG | PALLAS

Funded by the European Union

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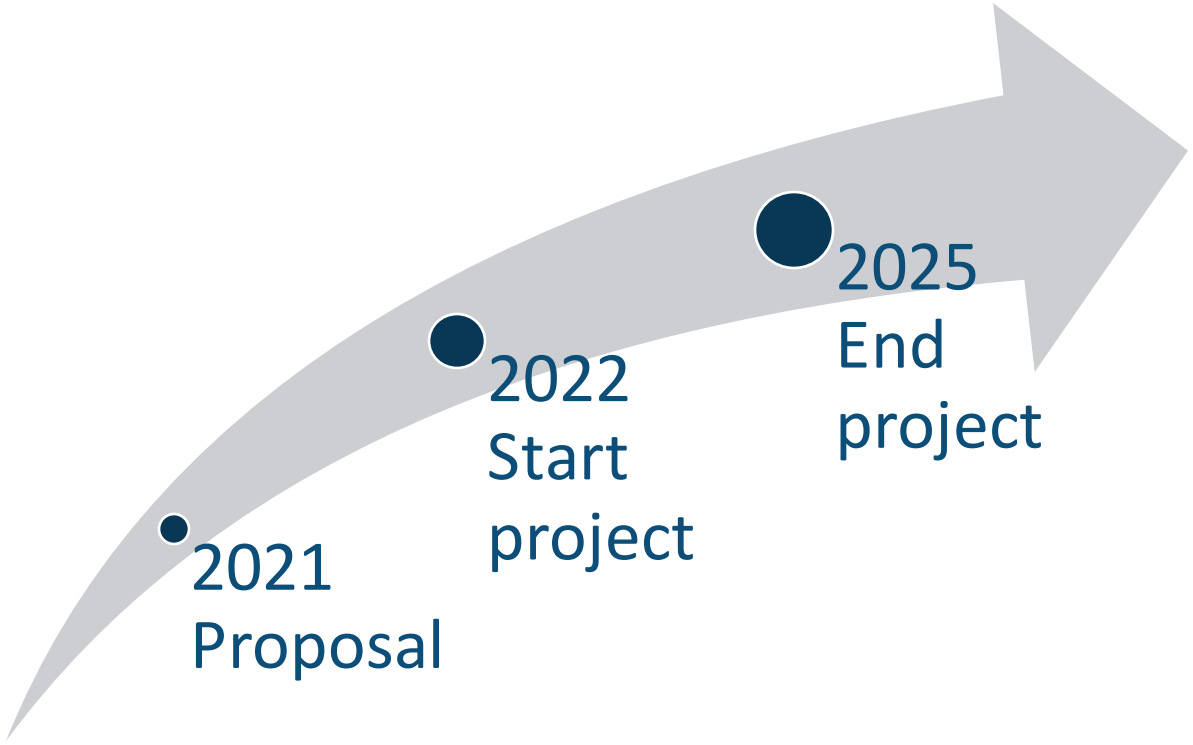
INTRODUCTION

- AIM - SECURE project aims to make a major contribution to the sustainability of medical isotope production and its safe application in Europe.
- FOCUS - It is focusing on promising developments in the design of irradiation targets, production routes for existing and new isotopes in nuclear therapy and diagnostics.



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PROJECT PARTNERS

- Narodowe Centrum Badań Jądrowych (NCBJ) Poland
- Nuclear Research and Consultancy Group (NRG) Netherlands
- Institut Max von Laue – Paul Langevin (ILL) France
- Institut Jožef Stefan (JSI) Slovenia
- European Nuclear Education Network (ENEN) Belgium
- Energiatudományi Kutatóközpont (EK) Hungary
- European Federation of Organisations for Medical Physics (EFOMP) Netherlands
- Agenzia nazionale per le nuove tecnologie, l'energia e lo sviluppo economico sostenibile (ENEA) Italy
- Studiecentrum Voor Kernenergie / Centre D'etude De L'energie Nucleaire (SCK CEN) Belgium
- Evalion sro (EVALION) Czech Republic
- Budapesti Műszaki és Gazdaságtudományi Egyetem (BME) Hungary
- Clust-ER Industrie della Salute e del Benessere (Clust-ER Health) Italy
- Clusterul Regional Inovativ de Imagistică Moleculară şi Structurală Nord-Est (IMAGO-MOL) Romania
- Istituto Romagnolo per lo Studio dei Tumori Dino Amadori (IRST) Italy
- Université de Bretagne Occidentale (UBREST) France
- Univerzitetni KliničnI Center Ljubljana (UKCL) Slovenia
- Joint Research Centre (JRC) Germany
- National Nuclear Laboratory (NNL) United Kingdom

THE EXPECTED OUTCOMES (EOs)

EO1: Development of **optimised irradiation targets**, that are interchangeable to allow use within the whole EU supply network, and prioritising production with raw and source materials which are available and sustainable for the EU.

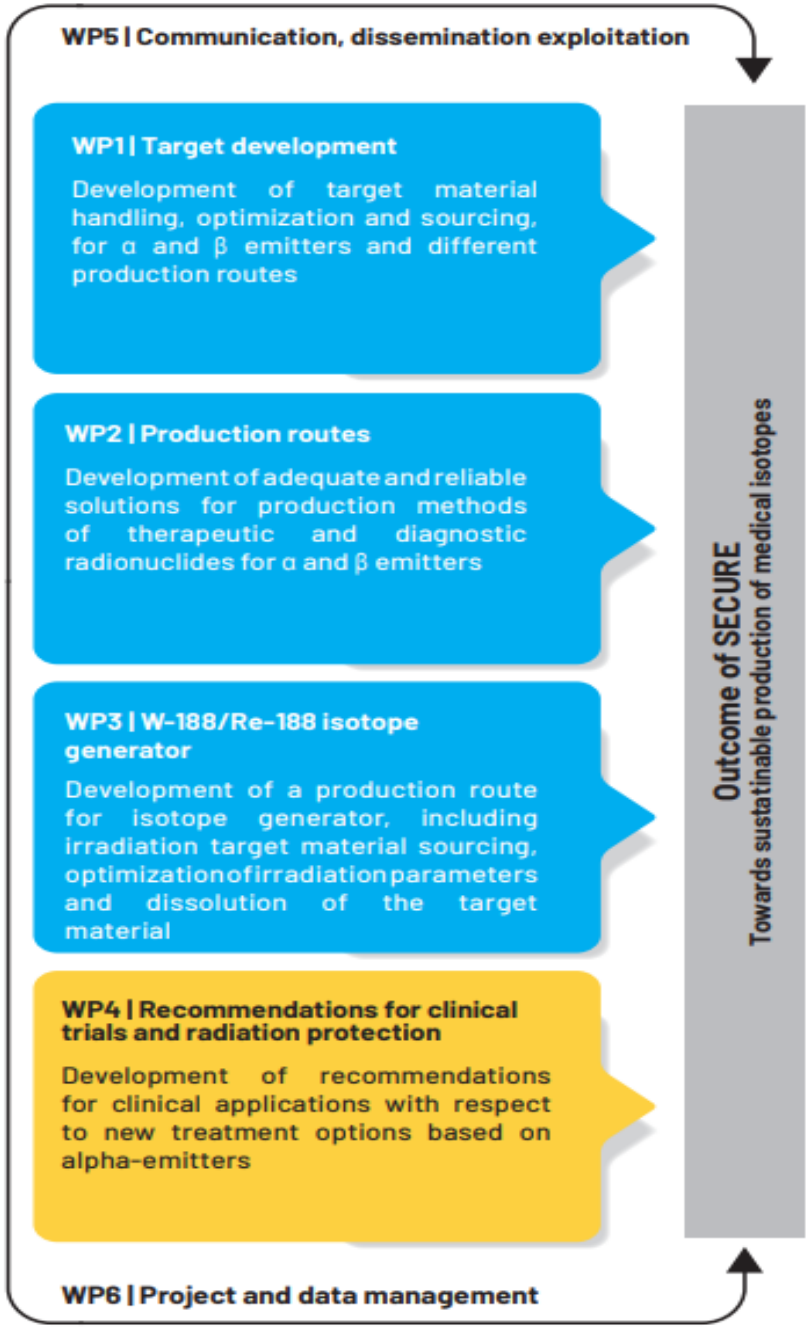
EO2: Development of **innovative routes of production of therapeutic and diagnostic radionuclides in the EU**, looking into reactor-based and alternative methods, including accelerator-based as well as separation / purification methods, also taking into account waste management options (EURAD), nuclear security and proliferation concerns.

EO3: Development of r**ecommendations for implementing clinical trials involving radiopharmaceuticals in the EU**, including the development of individual/specific organ dosimetry for the therapeutic applications (in target and non-target tissues).

EO4: Ensuring **an adequate supply of radioisotopes** for further research, clinical trials and clinical use with full implementation of radiation protection measures and with reduction of costs along the whole supply chain.

ORGANISATION OF WORK

- The project covers many production aspects of radionuclides for research and sustainable clinical use
- Project is split into 4 technical work packages



WP 1 – Target development

- Exchange experience and information
- Experimental effort to support handling, processing, purification and target manufacture
- Optimize the target composition and determination of production yields
- Provide general overview of target material needs and challenges

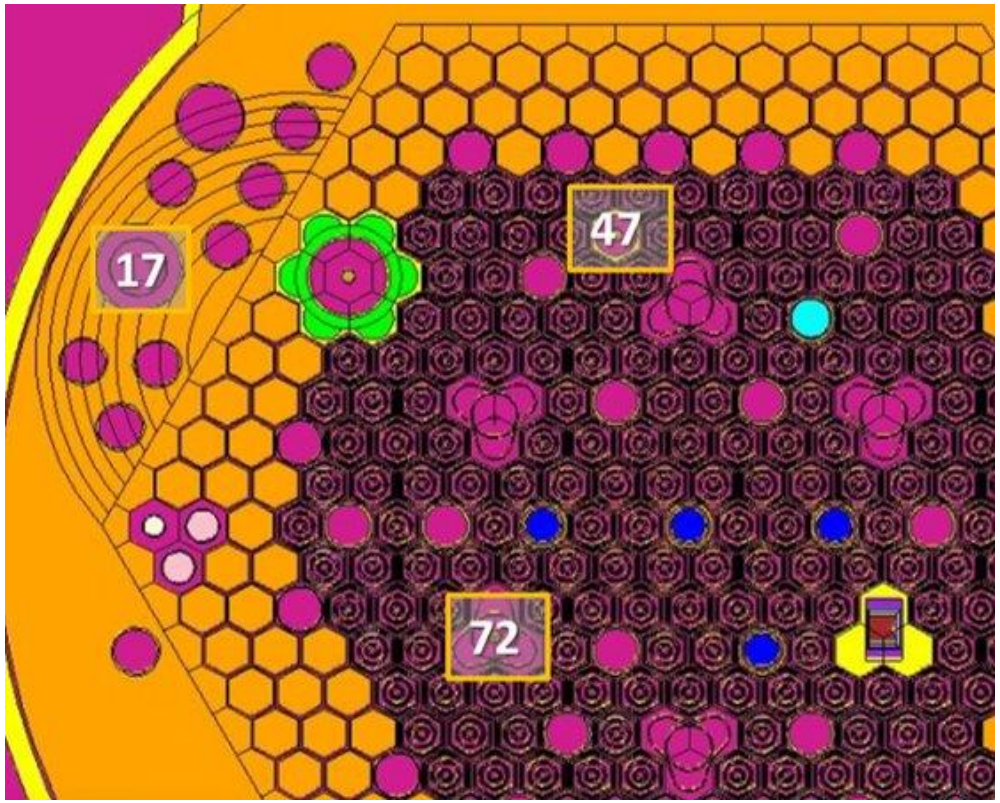
Cannot be done in hot cell.

Cannot be done in hot cell.

WP 2 – Production routes

Provide adequate and reliable solutions for production methods of therapeutic and diagnostic radionuclides selected in WP1.

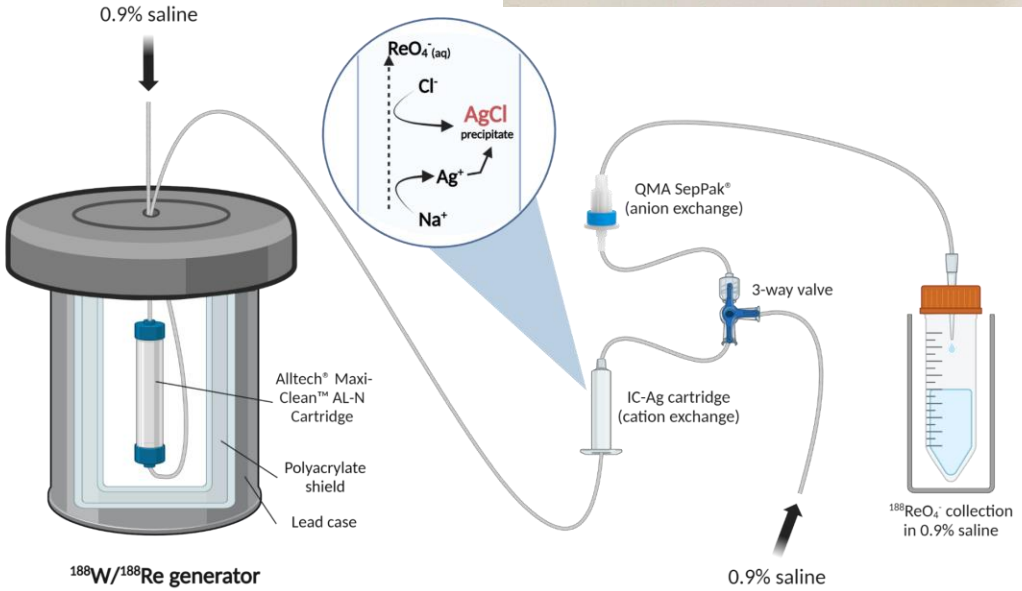
- Consider current production techniques and innovative methods
- Attention on the identification of current production methods reactor-based for α-emitters
- Compare current and innovative methods for large-scale production



WP 3 – W-188/Re-188 generator

To overcome the production issues of raw W-188 through the following objectives:

- to develop optimized W-186 irradiation targets that are interchangeable among the EU high-flux reactors,
- to develop simultaneously the corresponding optimized dissolution technologies.
- to make available W-188/Re-188 generators or batch activities of Re-188 respectively will revitalize the research towards Re-188 radiopharmaceuticals.



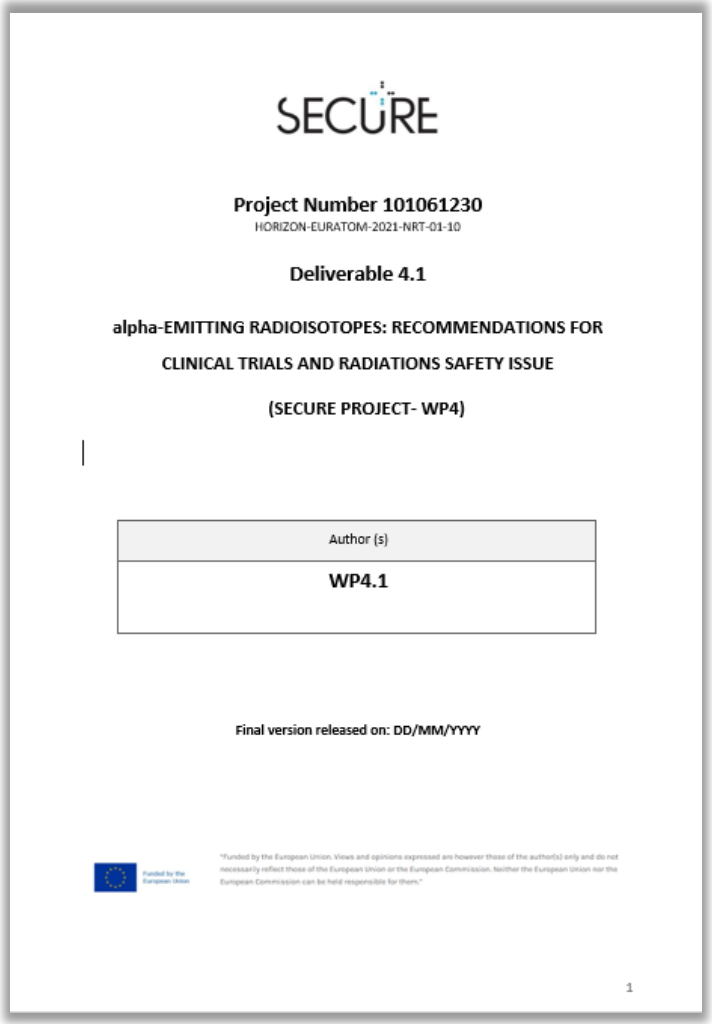
WP 4 – Recommendations for clinical trials and RP

The objectives of WP4 are as follows:

- Development of recommendations for clinical applications
- Benchmark analysis for RP measures in relation to radionuclide therapy considering the complete supply chain
- Development of recommendations to ensure the safety of new treatment options

T4.1 recommendations for clinical applications in the field of alpha emitter based therapy

Report WP 4.1, collecting the main physical and clinical characteristics of promising alpha emitter radiopharmaceuticals and finally reviewed by identified stakeholders of different institutions across Europe



SECURE

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Deliverable 4.1

alpha-EMITTING RADIOISOTOPES: RECOMMENDATIONS FOR CLINICAL TRIALS AND RADIATIONS SAFETY ISSUE

(SECURE PROJECT- WP4)

Author (s)
WP4.1

Final version released on: DD/MM/YYYY

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T4.1 a first look

7 alpha emitters were identified as future clinical key players

1. Physics characteristic and radiochemistry features
2. Preclinical and clinical studies

Isotope	Physics Characteristics	Radiochemistry	Preclinical studies	Clinical studies
Ac-225	ImagoMol	ImagoMol	ImagoMol	ImagoMol
Bi-213	IRST	IRST	IRST	IRST
At-211	UMCL; NCBJ	UMCL; NCBJ	UMCL; NCBJ	UMCL; NCBJ
Pb-212	NNL	NNL	NNL	NNL
Tb-149	UMCL; NCBJ	UMCL; NCBJ	UMCL; NCBJ	UMCL; NCBJ
Ra-223	IRST	IRST	IRST	IRST
Th-227	IRST	IRST	IRST	IRST

T4.2 Benchmark analysis for RP measures

i. inventory and identification (scheduled December 2023)

- ✓ First draft of the reported is completed

ii. scenario description (scheduled April 2024)

- ✓ Initial ideas on the formulation of the scenarios are discussed with the partners, and

iii. mitigation and optimization (scheduled October 2024)

- ✓ No work done yet

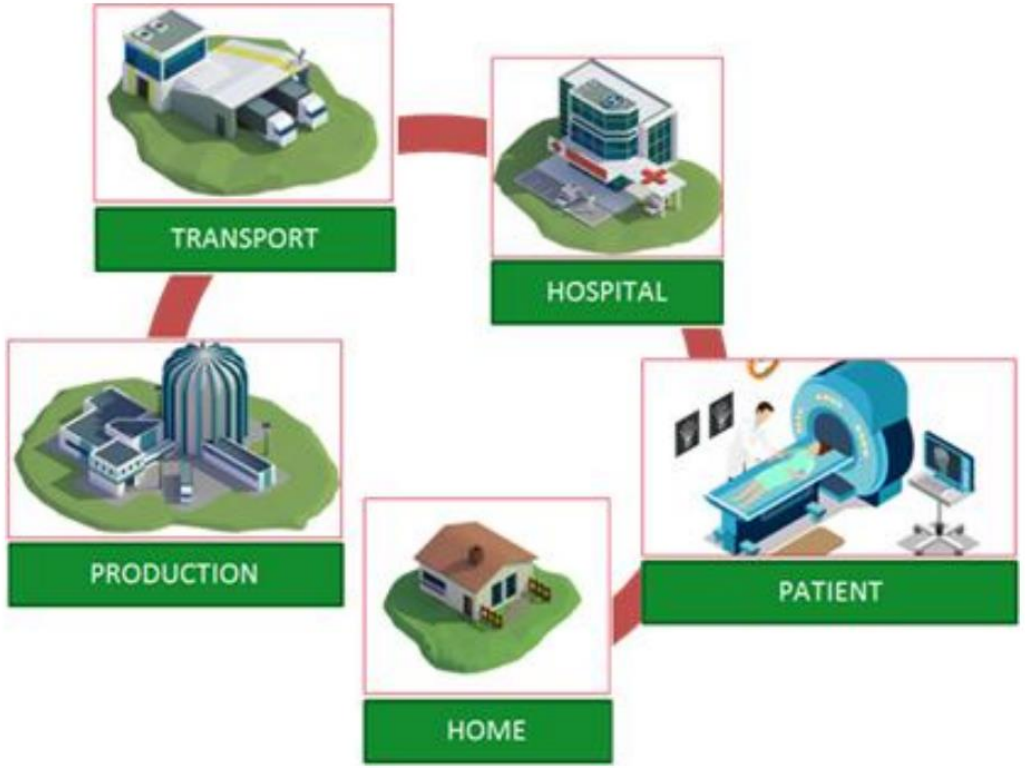


Figure 2: Product chain of medical isotopes from raw material to patient.

T4.3 Recommendations for treatment planning, delivery and dosimetry

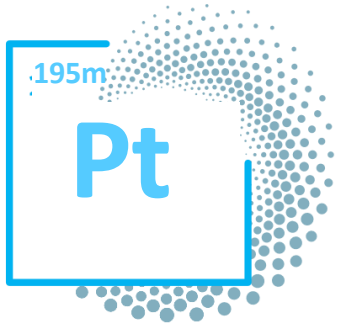
Challenges for alpha particles therapy dosimetry:

- ✓ Use of very low doses for imaging purposes
- ✓ Challenging imaging conditions depending on the alpha emitters used
- ✓ Investigate pharmacokinetics modeling
- ✓ Data availability

Monte-Carlo based framework

- ✓ Radionuclides
- ✓ Different clinical scenarios
- ✓ Imaging protocols
- ✓ Dosimetry

MARCH MEETING at NRG | PALLAS



PALLAS, building of a new reactor

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