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SNETP Forum

The SECURE project: towards a stable European supply of medical radioisotopes

SECURE

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Webpage SECURE Project:

Project objectives

SECURE project aims to make a major contribution to the sustainability of medical isotope production and its safe application in Europe. It is focusing on promising developments in the design of irradiation targets, production routes for existing and new isotopes in nuclear therapy and diagnostics. Isotopes critical in the success of nuclear medicine are selected and research activities are identified to address some of the major challenges in securing their future availability, with the objectives:

- To remove critical barriers along the production of selected alpha and beta emitting isotopes that restrict a sustainable production
- To develop a framework of guidance and recommendations that enables exploring the full clinical potential of alpha and beta particle therapy and its safe application
- To provide important lessons learned that act as a demonstration case for addressing issues in upscaling and sustained isotope production.

Expected impacts

- Identify and efficiently use current resources for new radionuclides, particularly alpha emitters and relevant beta-emitting theranostic radionuclides.
- Develop alternative technologies for the production of therapeutic radionuclides to improve patient treatment.
- Leverage multidisciplinary knowledge, including physics, chemistry, material science, target material machining, biology, radiobiology, radiopharmacy, and nuclear medicine.

Project Duration October 2022 – September 2025

Contact

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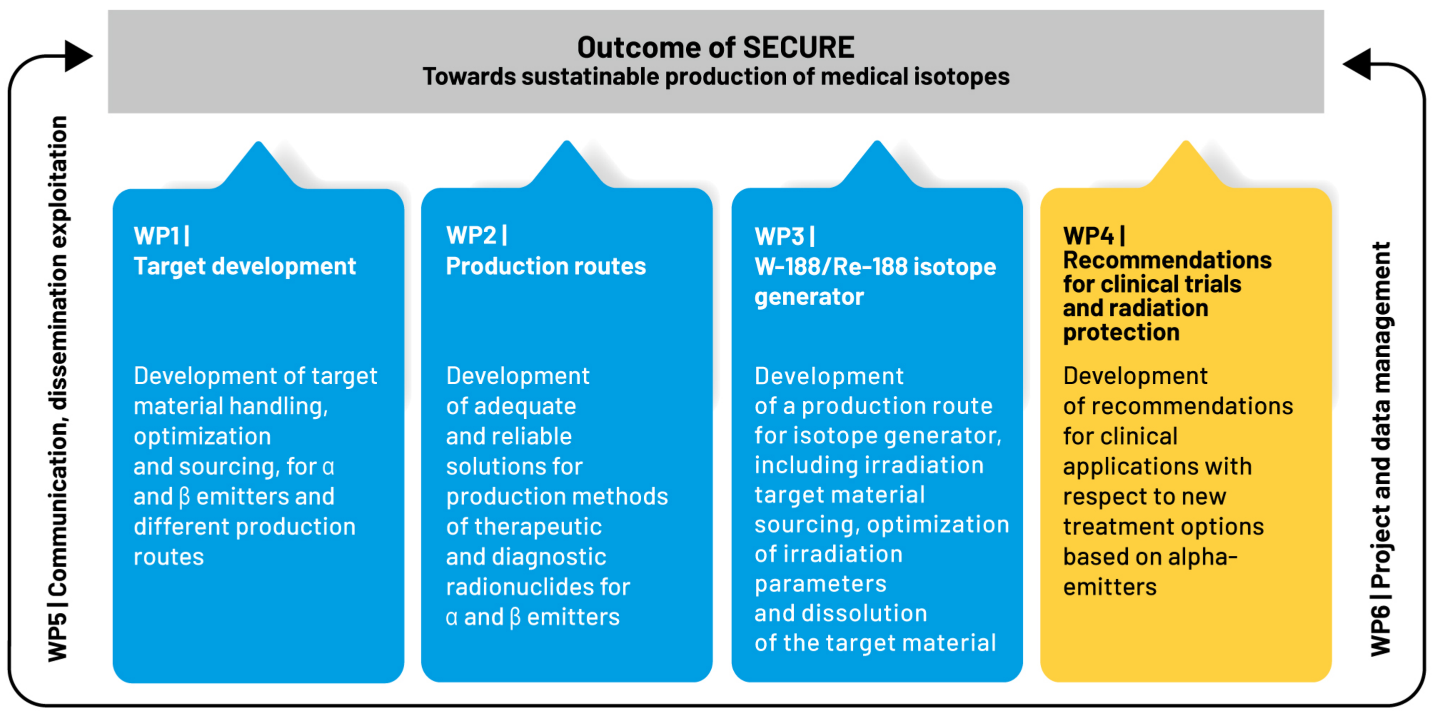
https://enen.eu/index.php/portfolio/secure-project/



Work Package 1

Research Problem: The production and application of nuclear medicine face critical challenges due to **infrastructural shortages** (irradiation facilities, shielded hot cells, enrichment facilities) and **legislation gaps**. Current regulations are often designed for nuclear power plants rather than for medical isotope production, creating inefficiencies in waste management and production processes.

Methodology: The SECURE project evaluates the value chains of emerging medical isotopes, identifying bottlenecks at a macro level. By analysing **production, purification, and clinical trial capacities**, SECURE aims to propose solutions for sustainable nuclear medicine.

Results:

1) **Investment needs** - Research and production are limited without increased infrastructure investments, which take years to materialise. Some partners have secured national funding, but delays persist.
2) **Regulatory challenges** - Current nuclear waste policies do not account for the distinct nature of medical isotope waste. SECURE investigates **recycling strategies** to minimise waste.
3) **Production pathways** - Different countries prioritise **reactor/cyclotron production** or **legacy waste decay**, depending on their available resources. Each approach offers distinct benefits in terms of flexibility, sustainability, and efficiency.

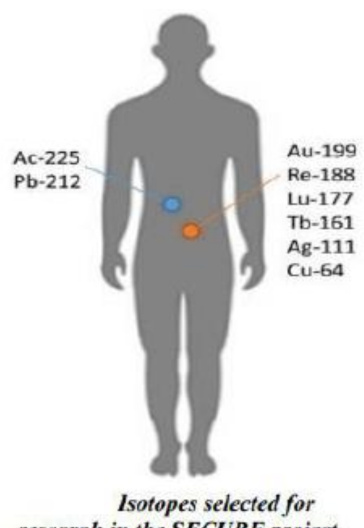
Work Package 2

Research Problem: The availability of key radionuclides for nuclear medicine is limited, impacting both **diagnostic and therapeutic** applications. Traditional **reactor-based production** methods must be optimised, and **accelerator-based alternatives** need further development to ensure a **stable, scalable, and cost-effective supply** of medical isotopes.

Methodology: WP2 investigates various **production routes** for crucial radionuclides: **Alpha emitters** (*e.g.*, Ac-225) for **Targeted Alpha Therapy (TAT)** (Task 2.1), **Beta emitters** (*e.g.*, Tb-161, Au-199, Ag-111) via research reactor-based methods (Task 2.2), **Cu-64 production** using fast neutron (n,p) reactions on Zn-64 as a cost-effective alternative to cyclotron-based methods (Task 2.3), **Pb-212 generator systems** to facilitate **on-site hospital use** (Task 2.4), and **Comprehensive supply chain evaluation** to mitigate radionuclide shortages (Task 2.5).

Results:

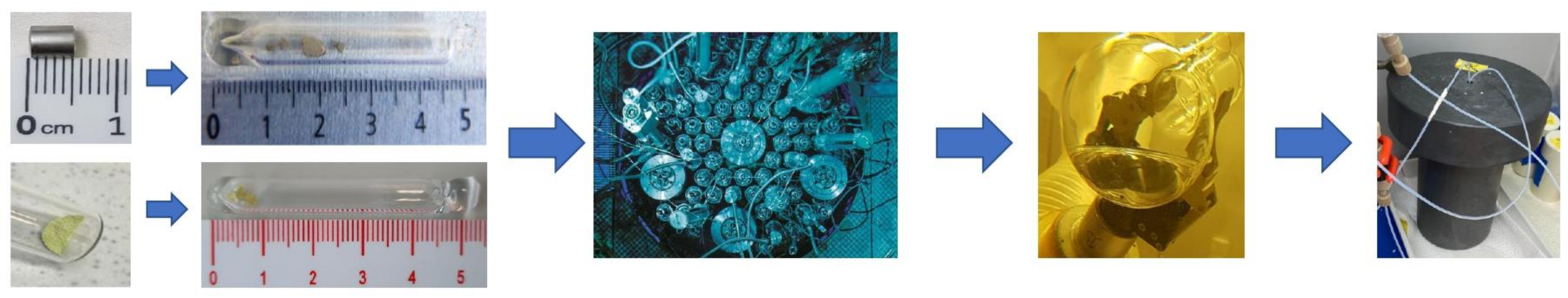
- **Alpha Emitters (Task 2.1):** Identified sustainable Ac-225 sources, including extraction from legacy waste and neutron-based production. The UK lacks research reactors but has neutron irradiation facilities that could be leveraged.
- **Beta Emitters (Task 2.2):** Developed **new reactor-based methods for Tb-161, Au-199, and Ag-111**, supported by Monte Carlo simulations (MCNP, FISPACT, CARP).
- **Cu-64 Production (Task 2.3):** A novel approach using Zn-64 targets with fast neutrons is being explored to reduce reliance on expensive Ni-64-based cyclotron production.
- **Pb-212 Generators (Task 2.4):** Generator-based Pb-212 production is being optimised for hospital-based labeling, considering logistics, material specifications, and maximum tolerated activity (MTA).



Isotopes selected for research in the SECURE project.
Blue: alpha emitting particles
Orange: beta emitting particles

Work Package 3

W-188/Re-188 isotope generator takes into consideration that Re-188 holds great potential for medical applications, but its use has been hindered by the limited and unreliable supply of W-188. WP3 aims to address this challenge by developing optimized W-186 irradiation targets that are compatible with high-flux reactors across Europe. This will enable the simultaneous development of efficient dissolution technologies.



Enriched W-186 oxide and metal targets

- Evaluation of **irradiation effects** on W target materials
- Address issues with shattered WO_3 ampoules by performing material studies on non-irradiated and irradiated material
- Development of advanced W targets

Reactor irradiation

- Perform test irradiations

Dissolution of target material

- Development of dissolution strategies of irradiated targets

W-188/Re-188 generator

- W-188/Re-188 "R&D generator" design and supply of Re-188

Work Package 4

Research problem: Cancer continues to be a leading cause of mortality worldwide, with traditional treatments facing limitations, particularly against metastatic forms. Targeted Alpha Therapy (TAT) presents a promising alternative by delivering high-energy alpha particles directly to cancer cells, minimising damage to surrounding healthy tissue. However, the clinical application of TAT is hindered by challenges such as the scarcity of suitable alpha-emitting radionuclides and logistical complexities associated with their use.

Methodology: The partners conducted an in-depth analysis of the current landscape of TAT, focusing on: 1) evaluating the unique properties and therapeutic potential of alpha-emitting radionuclides; 2) identifying existing challenges in the production, availability, and clinical application of these radionuclides; and 3) developing strategic recommendations to overcome these challenges and enhance the clinical adoption of TAT.

Results: To fully harness the potential of TAT in cancer treatment, the following seven recommendations have been proposed: **1) Great Potential**: Alpha-emitting radionuclides show promising results in clinical trials, signaling significant potential for patient benefits. **2) Secure Supply**: Progress in clinical trials relies on a steady supply of high-quality radionuclides. Support for production and scalability is essential. **3) Safety First**: Consider off-target effects and radioactive progeny in dosimetry and radiation safety for trial designs. **4) Optimised Agents**: Select chelating agents or precursors that ensure stability and minimise off-target effects, accounting for radioactive progeny release. **5) Standard Dosimetry**: Include standardised dosimetry measurements in clinical trials to ensure accuracy. **6) Unified Reporting**: Standardise trial protocols and reporting methods to optimise benefits from ongoing clinical trials. **7) Support More Trials**: Encourage further clinical trials to expand data, enhance understanding, and identify the most effective radionuclides for specific cancer types.

Conclusions

- SECURE fosters European cooperation to **streamline isotope production**, tackle bottlenecks, and exchange best practices. SECURE acknowledges that **policy adjustments and strategic investments** in infrastructure and legislation are crucial to ensuring the stable and safe supply of medical isotopes, ultimately benefiting cancer patients across Europe.
- WP2 ensures a **strong and reliable supply chain** for nuclear medicine radionuclides, following EU Good Distribution Practices (GDP) to **prevent shortages**. By integrating reactor and accelerator-based production, SECURE is **enhancing theragnostic capabilities**, bridging research gaps, and improving access to life-saving nuclear medicine across Europe.
- WP4 is currently finalising a **benchmark analysis for RP measures** related to alpha particle therapy, and creating safety guidelines for new treatment options involving alpha particle emitters. Together with the above recommendations for clinical trials, SECURE will contribute to **strengthening the safety of nuclear medicine for all the individuals involved** along the value chain, from manufacturers to medical staff and patients.

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