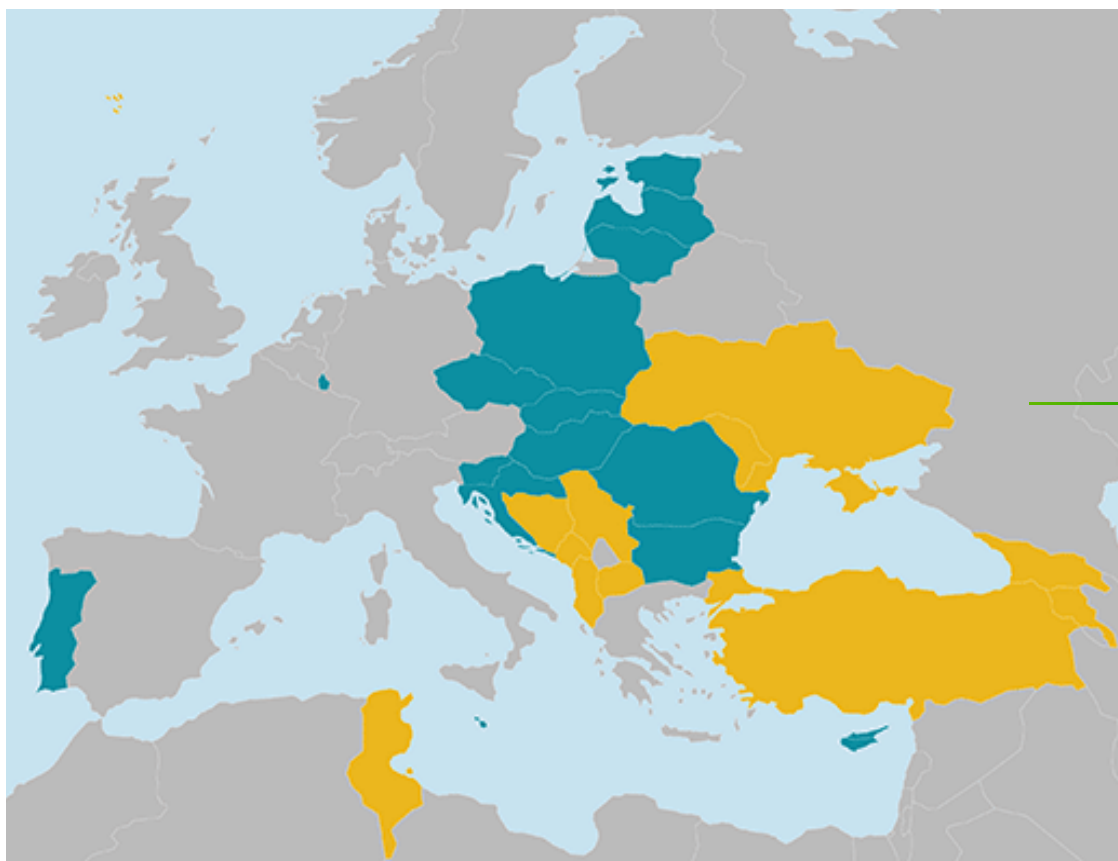

Situation in Widening Countries and Ambitions

Alpha therapy (Targeted Alpha Therapy or TAT) is an emerging field with strong potential

*When looking at **widening countries that already have cyclotron facilities**, the situation becomes both more promising and complex.*

Prof. Emilija Janeik-Ivanovska, PhD
Faculty of Medical Sciences
Laboratory of Radiopharmacy
Department of Drug Analysis and Pharmaceutical Chemistry
Goce Delcev University, Stip, Republic of N. Macedonia

Widening Countries EU Member States and associated countries



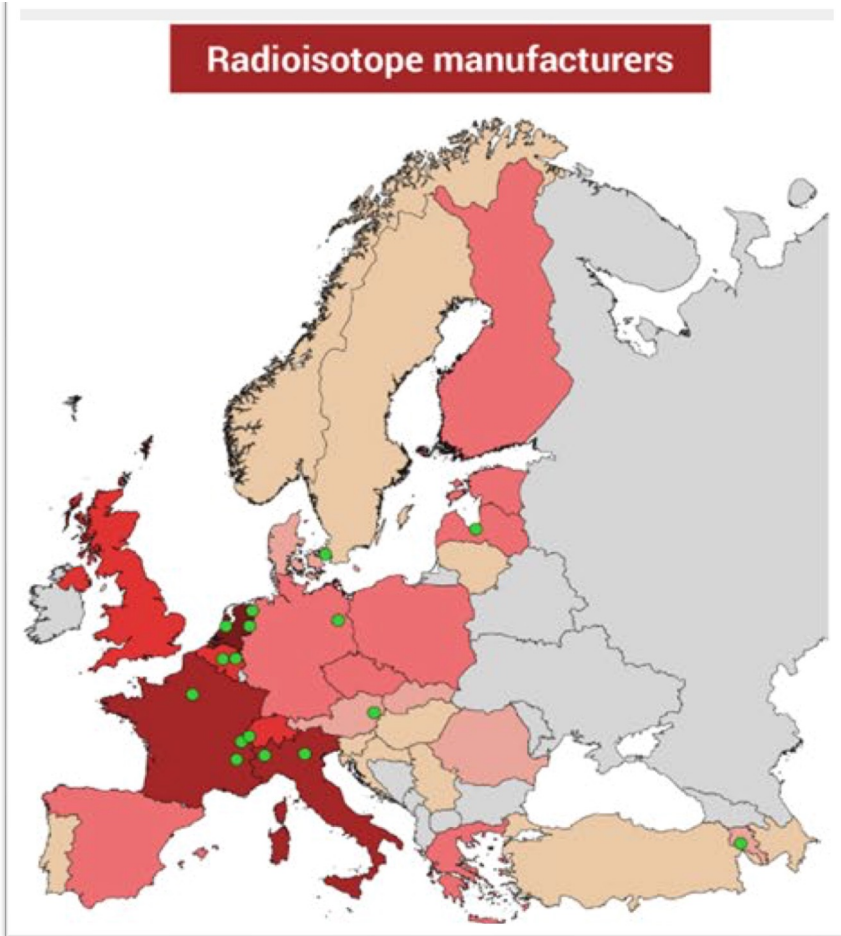
EU Member States

- Bulgaria
- Croatia
- Cyprus
- Czech Republic
- Estonia
- Greece
- Hungary
- Latvia
- Lithuania
- Malta
- Poland
- Portugal
- Romania
- Slovakia
- Slovenia

List of Associated Countries* eligible for hosting a Widening coordinator is:

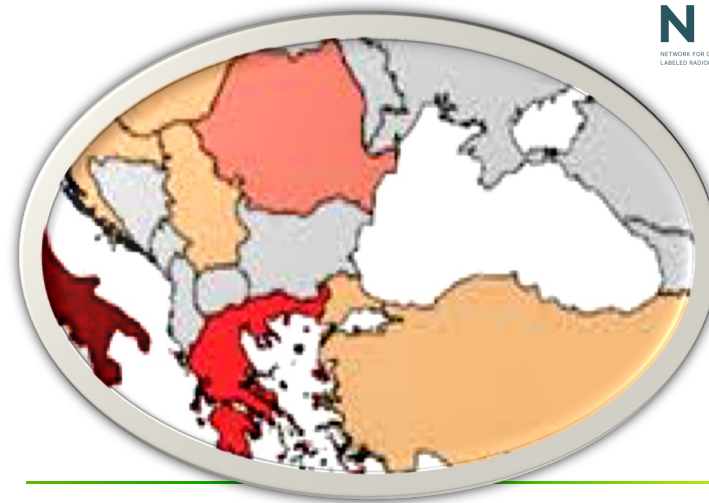
- Albania
- Armenia
- Bosnia and Herzegovina
- Faroe Islands
- Georgia
- Kosovo**
- Moldova
- Montenegro
- Morocco
- North Macedonia
- Serbia
- Tunisia
- Turkey
- Ukraine

Radioisotope manufacturers



Survey respondent map with representation by institutional type

Radzina M, et al. Novel radionuclides: demand, production and distribution for translational research in Europe. EJNMMI Radiopharm Chem. 2024 Dec 18;9(1):85

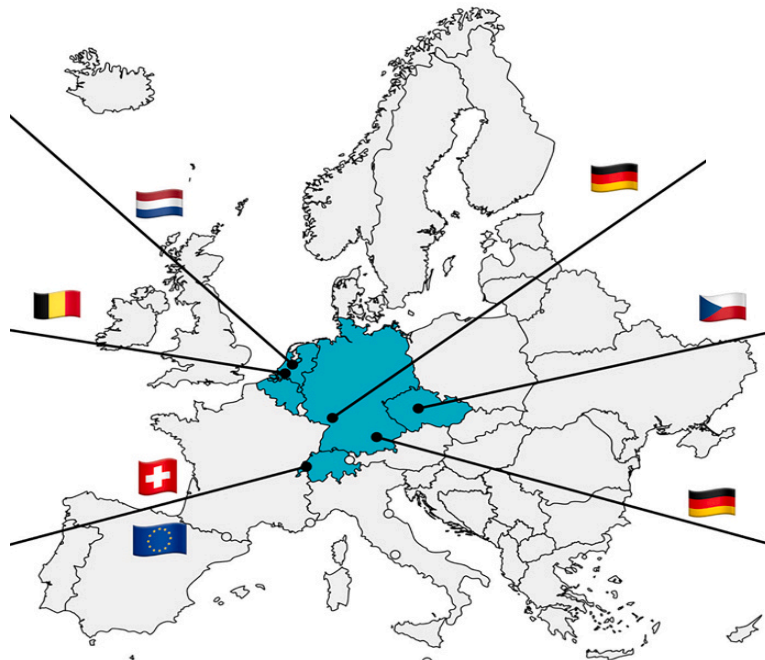


The **Balkan countries** have potential for developing Astatine-211 production due to growing healthcare needs, research capacity, and EU funding opportunities.

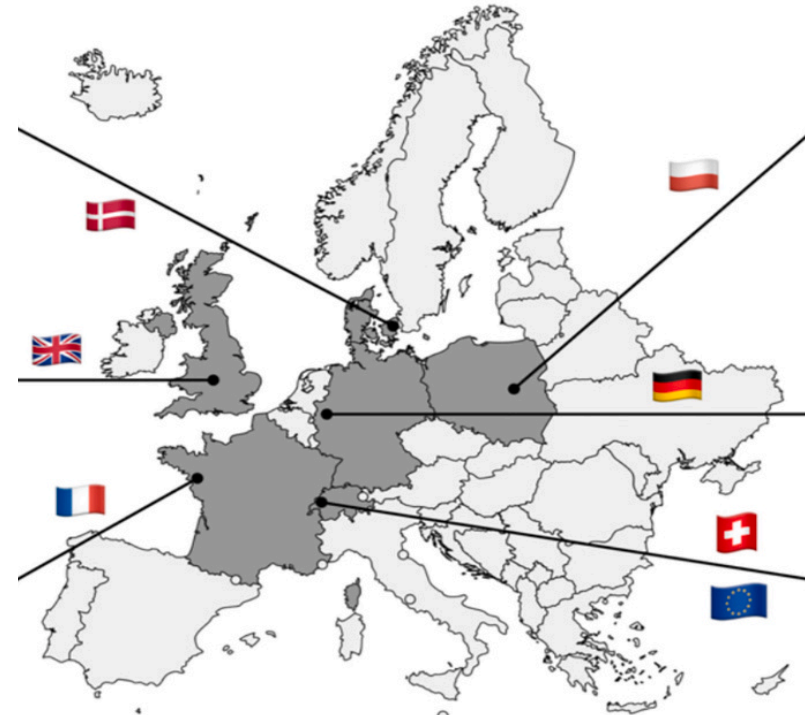
Challenges: **high initial investment, regulatory complexity,** need for specialized workforce, and logistical constraints due to the short half-life of the isotope.

Strategic collaboration, governmental support, and adherence to safety standards are key to realizing this goal.

Alpha Atlas – what is missing ...



^{225}Ac (and ^{213}Bi) atlas:



^{211}At atlas

Tosato M, Favaretto C, Kleyhans J, Burgoyne AR, Gestin JF, van der Meulen NP, Jalilian A, Köster U, Asti M, Radchenko V. **Alpha Atlas: Mapping global production of α -emitting radionuclides for targeted alpha therapy.** Nucl Med Biol. 2025

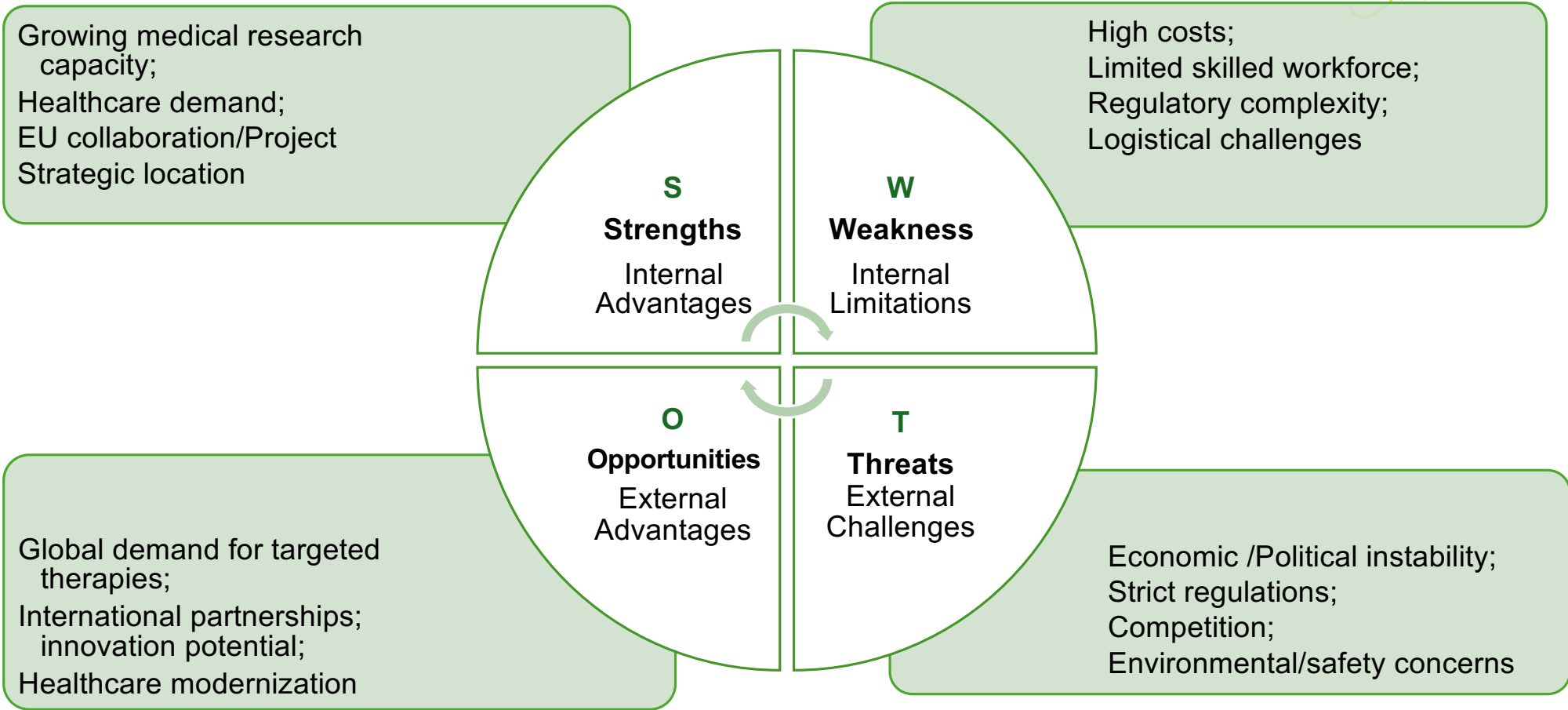
NOAR EUROPE MEETING, 03-05/11/2025, NANTES

The current status in the Balkan region since.....



Country	Population	PET/CT	PET/CT per 100 000 inhabitants	Cyclotron Situation can be changed
Bulgaria	7 000 000	6	0,08	2
Serbia	8 000 000	2	0,02	0
Monte Negro	628 000	0	0	0
Macedonia	2 000 000	1	0.05	1
Albania	2 800 000	0	0	0
Kosovo	1 800 000	0	0	0
Greece	10 000 000	12	0.12	2
Croatia	4 000 000	5	0,125	1

SWOT Analysis: Production of Therapeutic Isotopes (Astatine-211) in the Balkan countries



PESTLE Analysis: Production Potential of Therapeutic Isotopes (Astatine-211) in the Balkan countries



P	Political Factors:	Government Support for Nuclear Medicine: Regulatory Environment: Nuclear materials are heavily regulated Regional Stability.
E	Economic Factors:	Investment Costs: Establishing a cyclotron or nuclear reactor capable of producing Astatine-211 requires significant capital. Economic feasibility studies are essential. Healthcare Market Demand: Growing demand for targeted alpha therapy (TAT) and precision oncology in the region could justify investment. Funding Opportunities: EU grants, international partnerships, or private investments support infrastructure and R&D.
S	Social Factors:	Public Awareness and Acceptance: Knowledge about nuclear medicine and targeted therapies is limited. Skilled Workforce: Availability of trained medical staff is crucial - especially for clinical application. Healthcare Needs: Rising cancer incidence in the region could drive demand for novel therapies
T	Technological Factors:	Cyclotron and Radiochemistry Infrastructure: Innovation Potential: Collaboration with universities and research institutes Distribution Technology: Short half-life (~7.2 hours) of Astatine-211 requires efficient logistics
L	Legal Factors:	Nuclear Regulatory Compliance: Strict adherence to international and national nuclear safety standards Radiation protection laws Cross-border Transport Regulations: Legal frameworks for transporting radioactive isotopes within the Balkans and to neighboring regions need to be addressed
E	Environmental Factors:	Radioactive Waste Management: Sustainability Practices: Local Environmental Impact:

Current Context and Development Imperative - Ambitions



Building Regional Expertise and Access in Nuclear Medicine through Balkan and Southeast Europe Collaboration

Positioning of R.N.Macedonia as a regional distribution and production HUB for alpha therapeutic isotopes/ radiopharmaceuticals (Astatine-211)

Existing PET centre possesses substantial infrastructure and an opportunity for strategic expansion:

- **Strong strategic potential:** the convergence of demand growth in targeted alpha therapy, a regional supply gap,
- **The chance** to be first in a less-crowded region, and the ability to build a cost-efficient centre.
- **Existing full GMP Radiopharmaceuticals production site** (3 production areas – one dedicated only for therapeutic purpose) – and two separate QC laboratories - idea of centralized **RADIOPHARMACY**



PET center, Skopje – What we have



GMP production laboratory for FDG



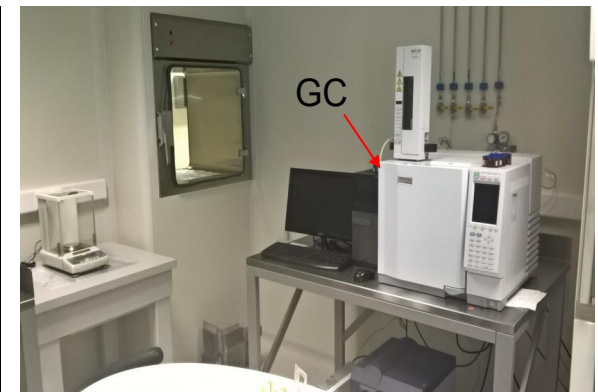
GMP production laboratory for 11C, ...68Ga



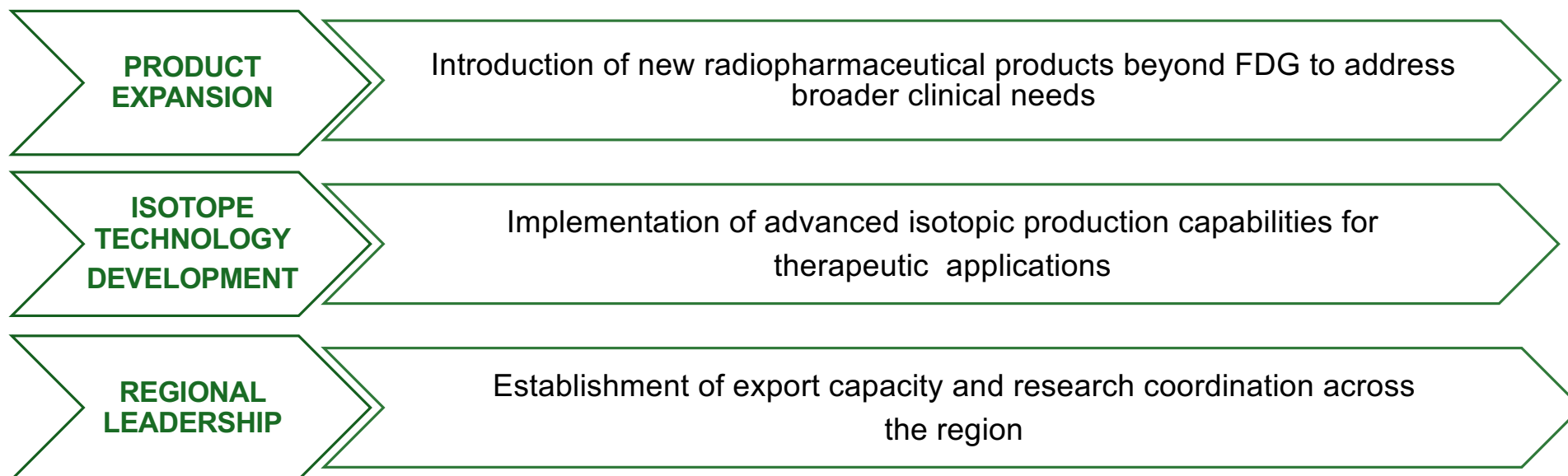
GMP therapy laboratory



Quality Control laboratory 1/2



Strategic Objectives – Feasibility study



This strategic approach will position the country as a regional centre of excellence of radioisotope/ radiopharmaceutical production (both PET and alpha) and in advanced nuclear medicine

Sustainability

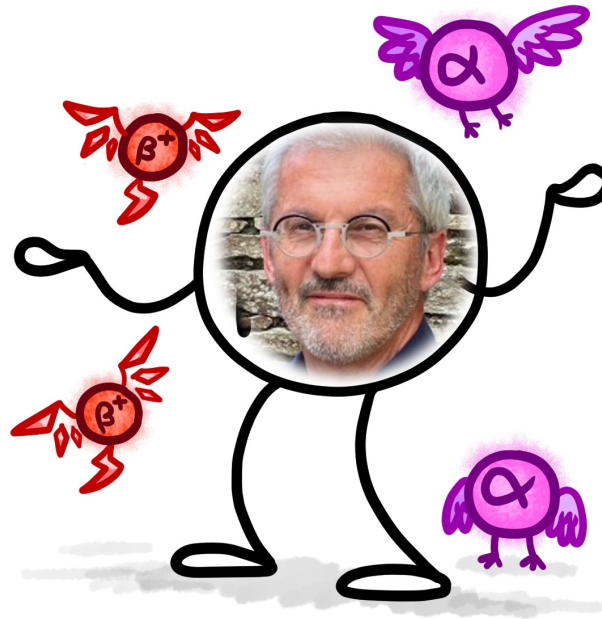


The long-term sustainability of the initiative will be ensured through:

- Strong institutional partnerships with EU and global organizations/partners
- Development of a self-sufficient radiopharmaceutical production system,
- Regulatory alignment with EU standards,
- Continuous training and knowledge transfer to local professionals,
- Economic sustainability through regional distribution, industry collaboration, and foreign investment

This ensures that the R. N. Macedonia becomes a recognized partner in the EU nuclear medicine landscape and a regional leader in radiopharmaceutical production including Astatine-211

Great group



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