FISA EURADWASTE 2025

SNETP Forum

AlphaMet - Metrology for emerging targeted alpha therapies at NCNR RC POLATOM
EURAMET project No. 22HLT03

AlphaMet – Metrology for Emerging Targeted Alpha Therapies

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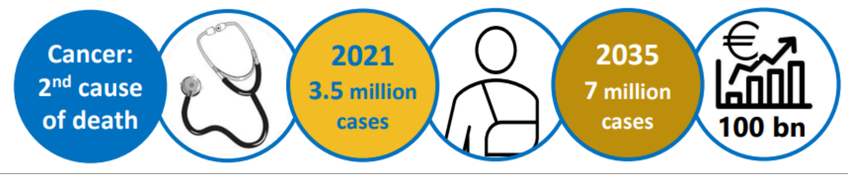
Drivers and needs

EUROPE'S BEATING CANCER PLAN ENCOURAGES THE DEVELOPMENT OF PERSONALISED RADIATION THERAPIES



- $^{223}RaCl_2$ is the first and only α-emitter with marketing authorisation ➔ its success led to increased investment in targeted alpha therapies (TAT) ➔ other α-emitters are undergoing clinical trials showing promising outcomes in patients not responding to β-emitters
- However, robust radioactivity standards, methods to quantify the activities and absorbed doses in tumours and organs at risk are not available ➔ no traceability, unknown uncertainties, accuracy and reproducibility of measurements in TAT, in contrast to ICRU96 recommendations
- The Basic Safety Standards (BSS) EC Directive 2013/59/EURATOM mandates dosimetry for TAT

WP1: Activity standards and nuclear data

CURRENT STATE OF THE ART

- Revision of ^{223}Ra standards found that patients were being injected with 9% more activity than intended No fully validated standards available for emerging α-emitters
- Recommended activity accuracies < ± 5%, however presently unknown

Activity measurement instrumentation:
(a) Gamma counter
(b) Radionuclide calibrator

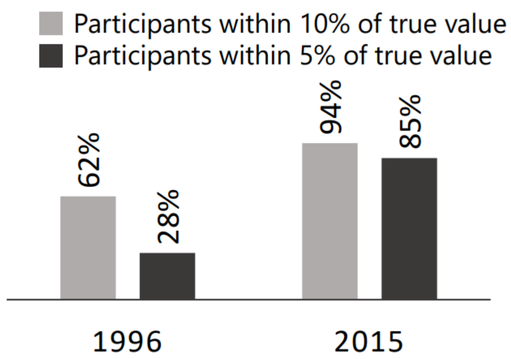
a) 

b) 

BEYOND STATE OF THE ART

- Development and dissemination of standards for ^{225}Ac, ^{212}Pb and ^{211}At
- Intercomparison of activity measurement capabilities in preclinical centres and hospitals to assess user needs

Potential improvements in activity measurement capabilities (e.g. ^{123}I)

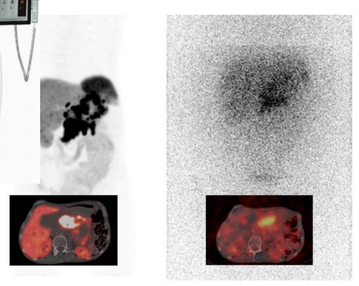


WP2: In-vivo SPECT quantification of activities

CURRENT STATE OF THE ART

- 3D quantitative SPECT (QSPECT) imaging is not established for α- emitters, but is essential for post- treatment verification (BSS)
- Low activities ➔ low count / resolution
- Unknown accuracy, reproducibility and uncertainties

SPECT



^{68}Ga-DOTATATE ^{225}Ac-DOTATATE

BEYOND STATE OF THE ART

- Assess feasibility/practicality of QSPECT for α-emitters (calibration, limits of detectability, quality control)
- Improve QSPECT with advanced processing techniques:

  (a) In-silico models for optimisation and generation of ground truth reference data

  (b) Reconstruction algorithms

- Harmonisation of α-QSPECT imaging ➔ multi-centre comparison exercise

WP5: Creating impact

Strong stakeholder support

PROJECT OUTPUTS ➔ OUTCOMES: EARLY IMPACT ➔ LONG-TERM WIDER IMPACT

Eight technical deliverables

Communication and dissemination:

- Project website, newsletters, social media…
- Stakeholder committee, 3 scientific workshops
- At least 9 open access publications and 10 presentations, and training material (ESMPE, ESMIT)
- Engagement with relevant scientific societies, committees and other European consortia

Exploitation of results:

- Uptake of deliverables, and open data by end-users (hospitals, pharmaceutical industry, nuclear medicine instrumentation manufacturers, researchers, etc.)

Uptake by private & public sectors:

- New and improved activity calibration services, and protocols to harmonise imaging and dosimetry in TAT

Standards, technical committees & regulations:

- Metrology: BIPM (international equivalence of standards for ^{225}Ac, ^{212}Pb and ^{211}At), EURAMET ionising radiation committee, DDEP (decay data), ICRM
- International uptake of scientific recommendations by IAEA, EANM, EARL, EFOMP, EURADOS, DICOM
- Support compliance with regulations: EC directive
- 2013/59/EURATOM, 2001/83/EC and 2001/20/EC

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- Economic/technical:
- New activity calibration services from NMI/DIs and improved traceability will reduce
- development costs and accelerate clinical translation:
- TAT market US$672 millions, to grow 37% by 2027
- AlphaMet will bring TAT a step closer to all other radiation therapy modalities ➔ traceable treatments
- Enable nuclear medicine departments (>1.5k in EU) to meet increasing demand and be cost-effective

Social: Improved quality of life for patients with cancer through traceable personalised dosimetry-based treatments compliant with ionising radiation regulations

Wider: Higher employment rates and wealth for society