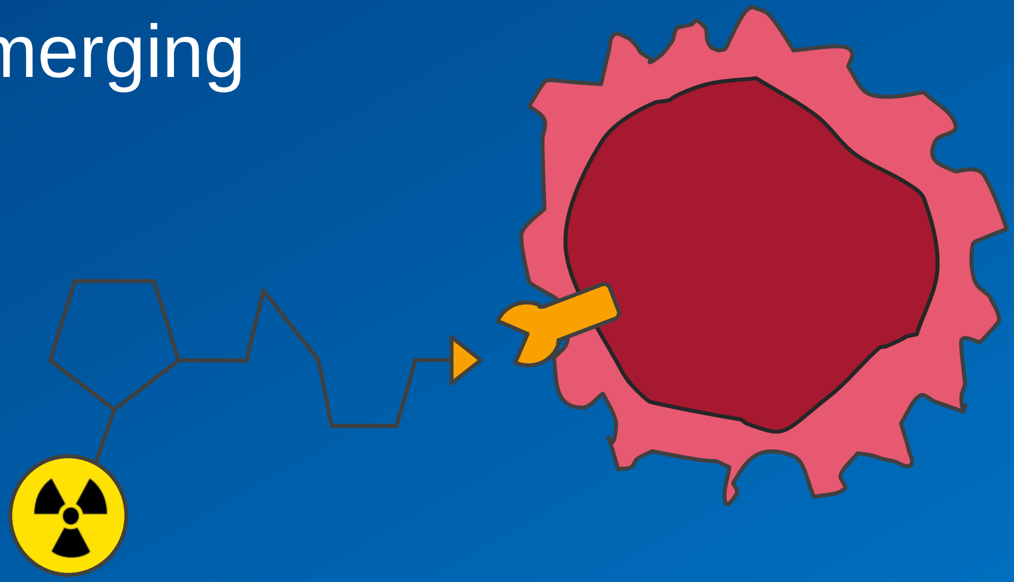
AlphaMet

A European project on metrology for emerging targeted alpha therapies



Ana Denis-Bacelar, PhD

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National Physical Laboratory, UK

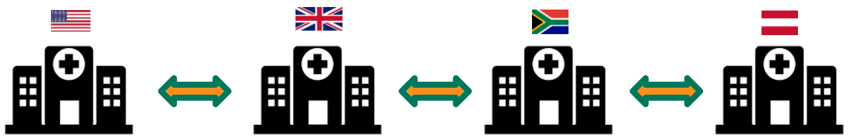
AlphaMet - CCRI RTQI International Workshop, 22-23 February 2024, BIPM, Paris

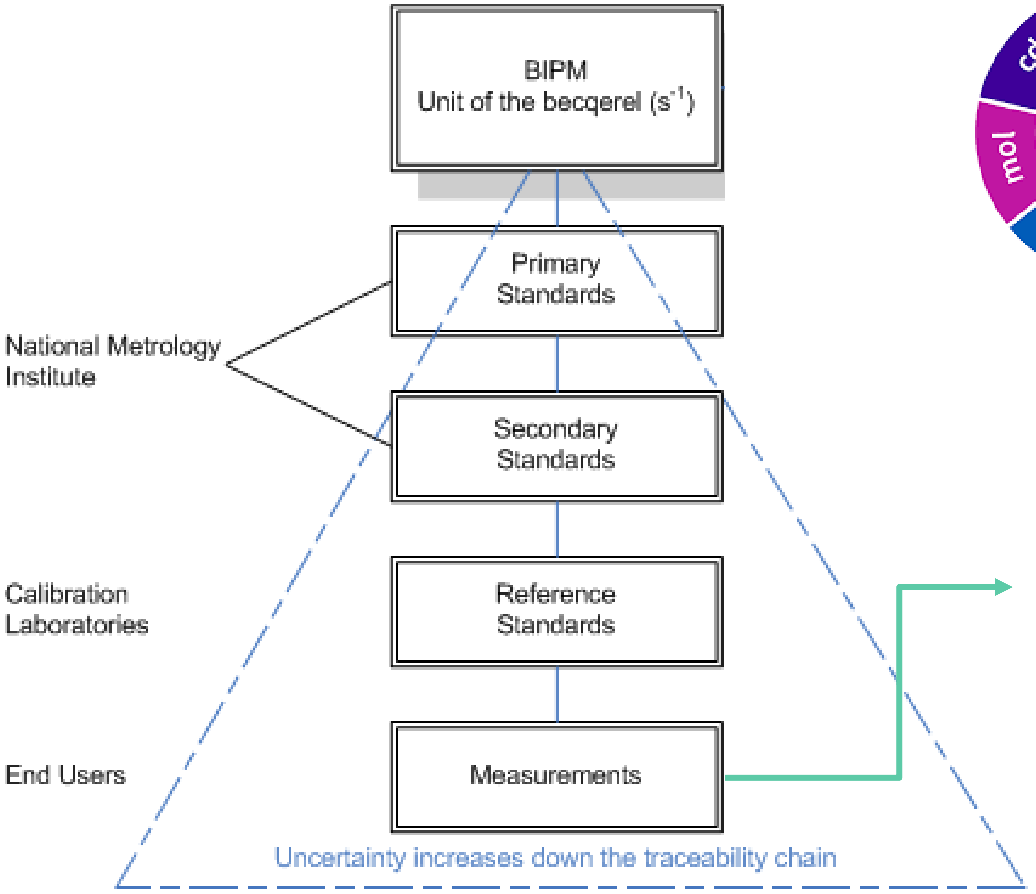
Why is metrology important?

AlphaMet
Metrology for Emerging Targeted Alpha Therapies
NPL

Metrology:

- provides an international measurement infrastructure which is stable over time, comparable between locations, and coherent
- establishes traceability chains by disseminating the value of accuracy, and therefore calculation of measurement uncertainties





Radionuclide calibrators

Metrological traceability in nuclear medicine

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Activity → Phantom /Patient → SPECT/PET → Reconstruction → 3D image (Fused) → VOI → TAC → Dosimetry/radiobiology

Bq / g → Volume → Gain → Linearity → EC → UC → AC (CT) → SC → PSF → OSEM → VOI → Partial Vol → Bq $_{VOI}$ → Bq*s $_{VOI}$ → Gy $_{VOI}$

$$u(A) \rightarrow u(m) \rightarrow u \rightarrow u \rightarrow u \rightarrow u \rightarrow u \rightarrow u \rightarrow u \rightarrow u \rightarrow u \rightarrow u \rightarrow u(A_{VOI}) \rightarrow u(D_{VOI})$$

Need to understand the measurements and associated uncertainties

History of MRT European metrology

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Supporting MRT dosimetry for over 10 years:

Current funding programme: http://www.metpart.eu/

EMRP
European Metrology Research Programme
Programme of EURAMET
The EMRP is jointly funded by the EMRP participating countries within EURAMET and the European Union

EMPIR EURAMET
The EMPIR initiative is co-funded by the European Union's Horizon 2020 research and innovation programme and the EMPIR Participating States

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2012 – 2015 → 2016 – 2019 → 2020 – 2023

MetroMRT
Metrology for Molecular Radiotherapy

MRT DOSIMETRY
Metrology for clinical implementation of dosimetry in molecular radiotherapy

PINICAL-MRT
Protocols for clinical impact in molecular radiotherapy

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First international guidelines on uncertainty calculations

European Journal of Nuclear Medicine and Molecular Imaging (2018) 45:2456–2474
https://doi.org/10.1007/s00259-018-4136-7

GUIDELINES

EANM practical guidance on uncertainty analysis for molecular radiotherapy absorbed dose calculations

Jonathan I. Gear[1] • Maurice G. Cox[2] • Johan Gustafsson[3] • Katarina Sjögreen Gleisner[3] • Iain Murray[1]
Gerhard Glatting[4] • Mark Konijnenberg[5] • Glenn D. Flux[1]

Received: 9 August 2018 / Accepted: 14 August 2018 / Published online: 14 September 2018
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EANM
EUROPEAN ASSOCIATION OF NUCLEAR MEDICINE

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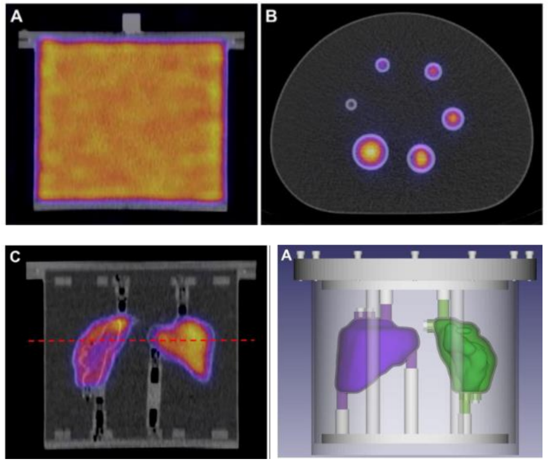
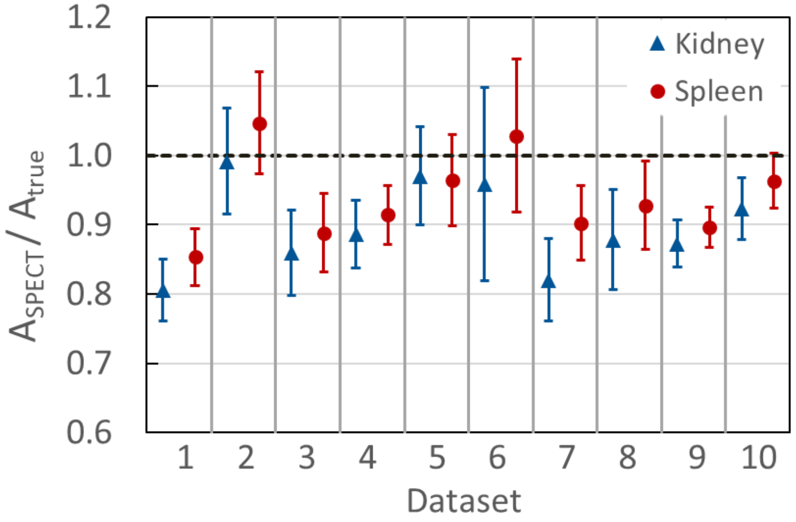
Towards harmonisation of ^{177}Lu quantitative imaging





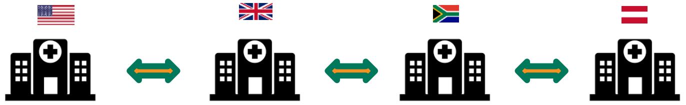
Tran-Gia et al. EJNMMI Physics (2021) 8:55
https://doi.org/10.1186/s40658-021-00397-0
EJNMMI Physics

ORIGINAL RESEARCH Open Access

A multicentre and multi-national evaluation of the accuracy of quantitative Lu-177 SPECT/CT imaging performed within the MRTDosimetry project

Check for updates

Johannes Tran-Gia[1*], Ana M. Denis-Bacelar[2], Kelley M. Ferreira[2], Andrew P. Robinson[2,3,4], Nicholas Calvert[3], Andrew J. Fenwick[2,5], Domenico Finocchiaro[6,7], Federica Fioroni[6], Elisa Grassi[6], Warda Heetun[2], Stephanie J. Jewitt[8], Maria Kotzassarlidou[9*], Michael Ljungberg[10], Daniel R. McGowan[8,11], Nathaniel Scott[8], James Scuffham[2,12,13], Katarina Sjögreen Gleisner[10], Jill Tipping[3], Jill Wevrett[2,12,13], The MRTDosimetry Collaboration and Michael Lassmann[1]



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Protocols for clinical impact in molecular radiotherapy

Towards harmonisation of ^{177}Lu quantitative imaging

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Results now used by EARL to establish an international accreditation programme for the harmonisation of SPECT ^{177}Lu imaging
➔ improve accuracy and reproducibility in multi-centre studies

RESEARCH4LIFE©

Tran-Gia et al. EJNMMI Physics (2021) 8:55
https://doi.org/10.1186/s40658-021-00397-0

EJNMMI Physics

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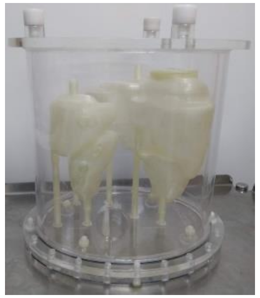
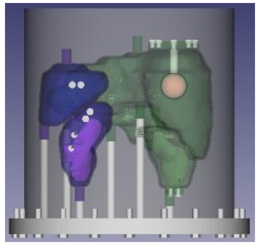
PINICAL-MRT

Protocols for clinical impact in molecular radiotherapy

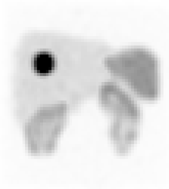
Quality assurance of dosimetry software

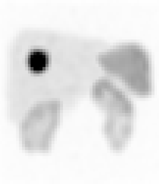




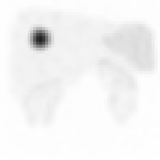

1 h


4 h


24 h


40 h


72 h

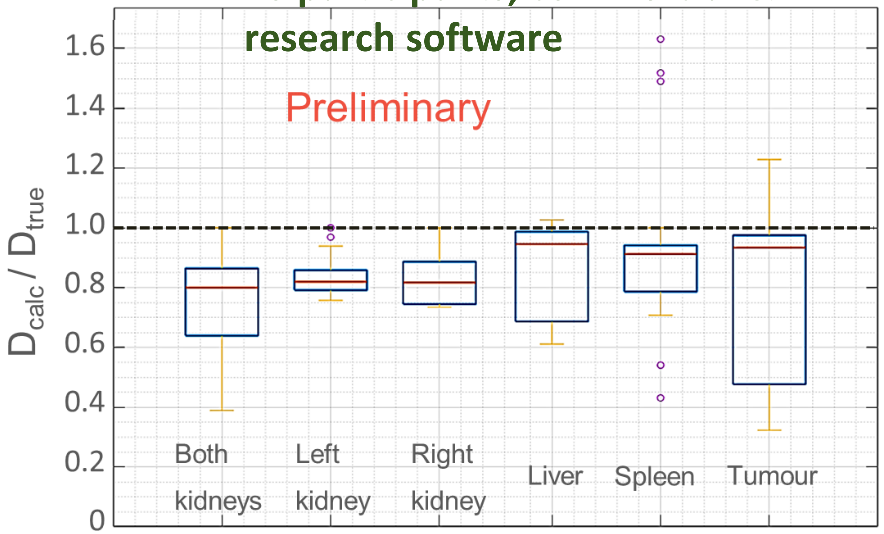

144 h

Reference dataset

Robinson *et al.*
Physica Medica 2023

https://osf.io/69nge/

10 participants, commercial & research software



Denis-Bacelar *et al.* In preparation

What next?

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Metrology for Emerging Targeted Alpha Therapies
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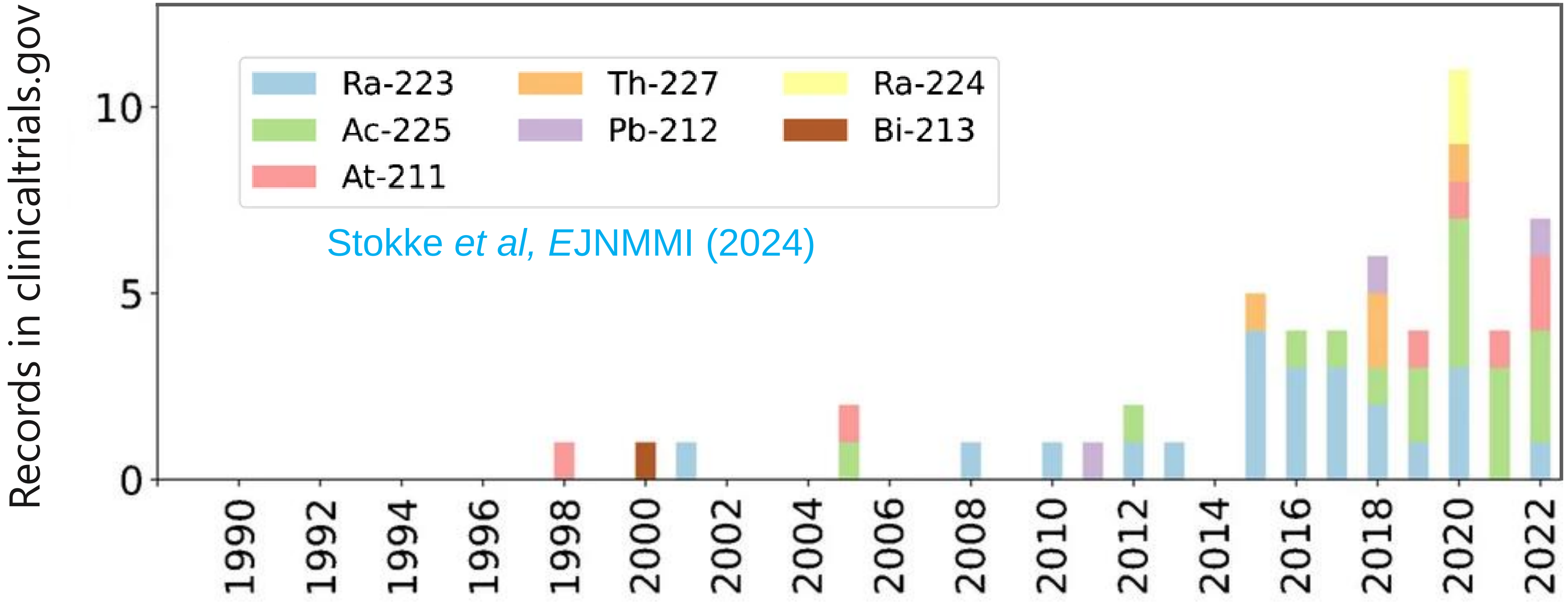
- $^{223}RaCl_2$ is the first and only α-emitter with marketing authorisation, leading to:
  - ➔ increased investment in targeted alpha therapies (TAT): US$ 672 million global market expected to grow 36.7% by 2027
  - ➔ other α-emitting therapies under development (^{225}Ac, ^{213}Bi, ^{224}Ra, ^{212}Pb, ^{211}At, ^{149}Tb)



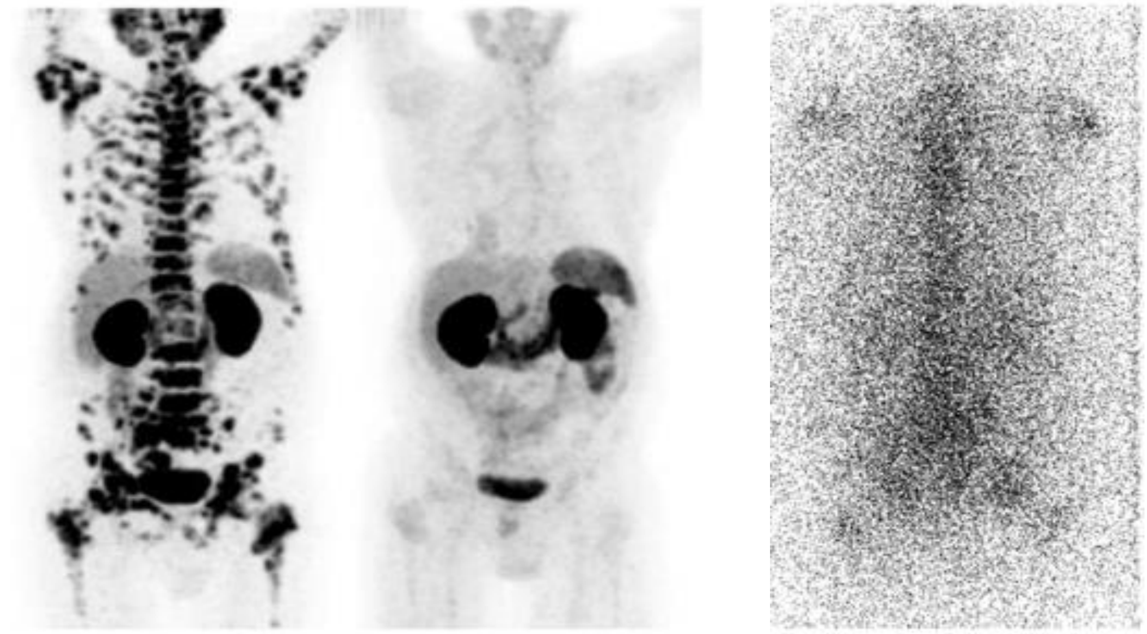
Stokke *et al*, EJNMMI (2024)

What next?

- However… robust radioactivity standards, good practice guides on activity and absorbed dose quantification are not available
- Therefore… presently no traceability, unknown uncertainties, accuracy and reproducibility of measurements in TAT
- The Basic Safety Standards (BSS) EC Directive 2013/59/EURATOM mandates dosimetry

AlphaMet
Metrology for Emerging Targeted Alpha Therapies

Pre- and post-treatment scans | Therapy scan



^{68}Ga-PSMA PET

^{225}Ac-PSMA SPECT

Kratochwil *et al*, JNM (2016)

AlphaMet aims to address the unique and unmet metrological challenges of alpha emitters and support the implementation of end-to-end traceability for alpha therapies before wide routine adoption

EUROPEAN PARTNERSHIP

Co-funded by the European Union

METROLOGY PARTNERSHIP

EURAMET

Consortium

- Eight metrology institutes (NMI/DI)

CZECH METROLOGY INSTITUTE | cea | GOBIERNO DE ESPAÑA – MINISTERIO DE CIENCIA E INNOVACIÓN – Ciemat Centro de Investigaciones Energéticas, Medioambientales y Tecnológicas | NPL National Physical Laboratory

ENEA AGENZIA NAZIONALE PER LE NUOVE TECNOLOGIE, L'ENERGIA E LO SVILUPPO ECONOMICO SOSTENIBILE | CHUV Centre hospitalier universitaire vaudois | sck cen | NATIONAL CENTRE FOR NUCLEAR RESEARCH ŚWIERK

- Eight clinical and research partners, and one affiliated entity

LMU KLINIKUM | BfS Bundesamt für Strahlenschutz | KU LEUVEN | UNIVERSITY OF GOTHENBURG

Osakidetza | biocruces bizkaia | Universitätsklinikum Würzburg | NHS Royal Surrey NHS Foundation Trust | Arronax Nantes

2.6 (1.9)M€, Sep 2023 – Aug 2026

AlphaMet: Technical Work Packages

AlphaMet
Metrology for Emerging Targeted Alpha Therapies

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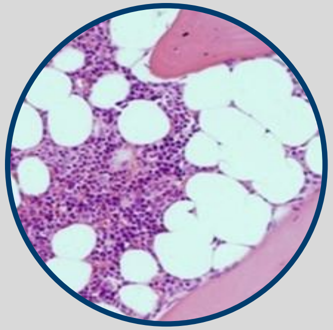
WP1
Standards

WP2
Activity

WP3
Absorbed dose



WP4
Bone marrow

End-to-end metrology

WP1 – Standards

Standards (^{225}Ac, ^{212}Pb, ^{211}At)

Measurement capabilities of end-users?

WP2 – Activity

QI of alpha emitters

Accuracy, reproducibility, uncertainties?

WP3 – Absorbed dose

Uncertainty analysis in biokinetic modelling

Macro to micro-dosimetry

WP4 – Bone marrow

Quantitative morphological imaging of the bone marrow (DECT & MRI)

WP1: Radioactivity standards

Challenges

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Metrology for Emerging Targeted Alpha Therapies

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- Revision of ^{223}Ra standards found that patients were being injected with 9% more activity than intended
- No fully validated standards available for other α-emitters

Measurement technique	Activity concentration/kBq g^{-1}
Primary methods	
CIEMAT/NIST efficiency traced LSC	52.37 ± 0.35
4π LS-γ digital coincidence counting with computer discrimination	52.34 ± 0.18
Weighted mean	**52.35 ± 0.16**
Secondary methods	
γ-spectrometry	51.97 ± 0.76
Ionisation chamber based on calibration factors of Bergeron et al. (2010)	47.5 ± 0.3
4π APPC (α)−γ coincidence counting	52.37 ± 0.40
4π APPC (α+β)−γ coincidence counting	52.5 ± 1.0

9% bias

Keightley J *et al.* (2015). ARI *95*, 114–121

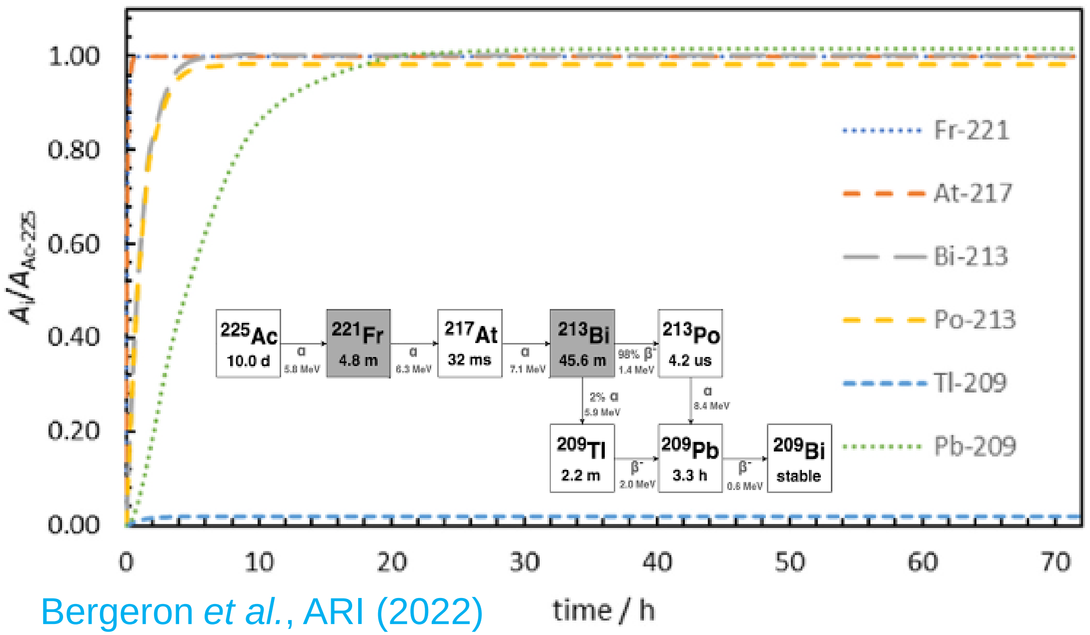
2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosage

The dose regimen of Xofigo is 50 kBq (1.35 microcurie) per kg body weight, given at 4 week intervals for 6 injections. Safety and efficacy beyond 6 injections with Xofigo have not been studied.

From 50 to 55 kBq/kg

- International guidance recommends that therapeutic administered activities should be accurate within ±5%,
- How well can end-users measure alpha emitters?



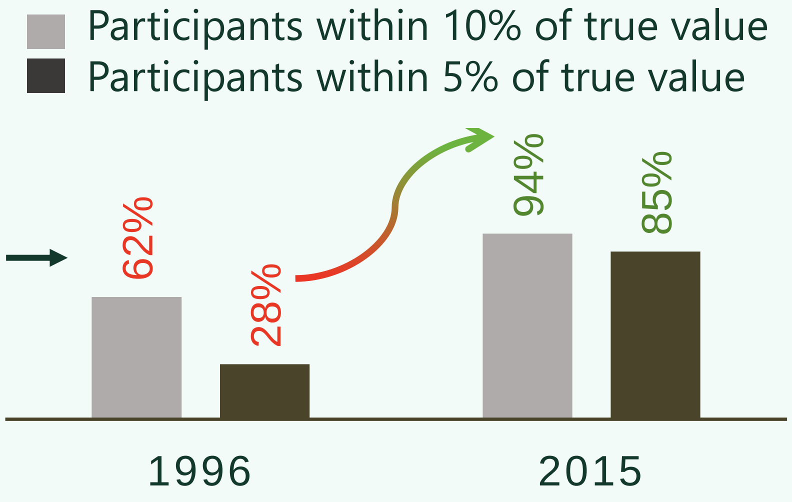
Bergeron *et al.*, ARI (2022)

WP1: Radioactivity standards

Beyond the start of the art

- Develop new primary (secondary) standards:
  - ^{225}Ac: **CEA**, **CMI**, ENEA, **NPL**, CIEMAT, **NCBJ**, **CHUV** (combined with CCRI KCWG)
  - ^{212}Pb: **CEA**, **CMI**, **NPL**, CIEMAT
  - ^{211}At: **CEA**, **CMI**, **CHUV**, **CIEMAT**
- Perform intercomparison exercise of activity measurement capabilities (radionuclide calibrators & gamma counters) at research and clinical settings to assess user needs (^{225}Ac)

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



Ferreira *et al.*, ARI (2016)

AlphaMet: Technical Work Packages

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WP1
Standards

Standards (^{225}Ac, ^{212}Pb, ^{211}At)

Measurement capabilities of end-users?

WP2
Activity

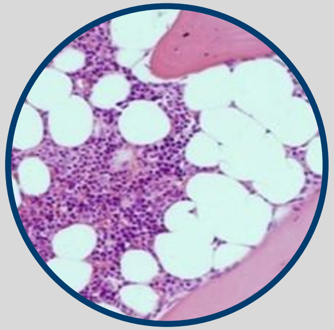
QI of alpha emitters

Accuracy, reproducibility, uncertainties?

WP3
Absorbed dose

Uncertainty analysis in biokinetic modelling

Macro to micro-dosimetry



WP4
Bone marrow

Morphological imaging of the bone marrow (DECT & MRI)

End-to-end metrology

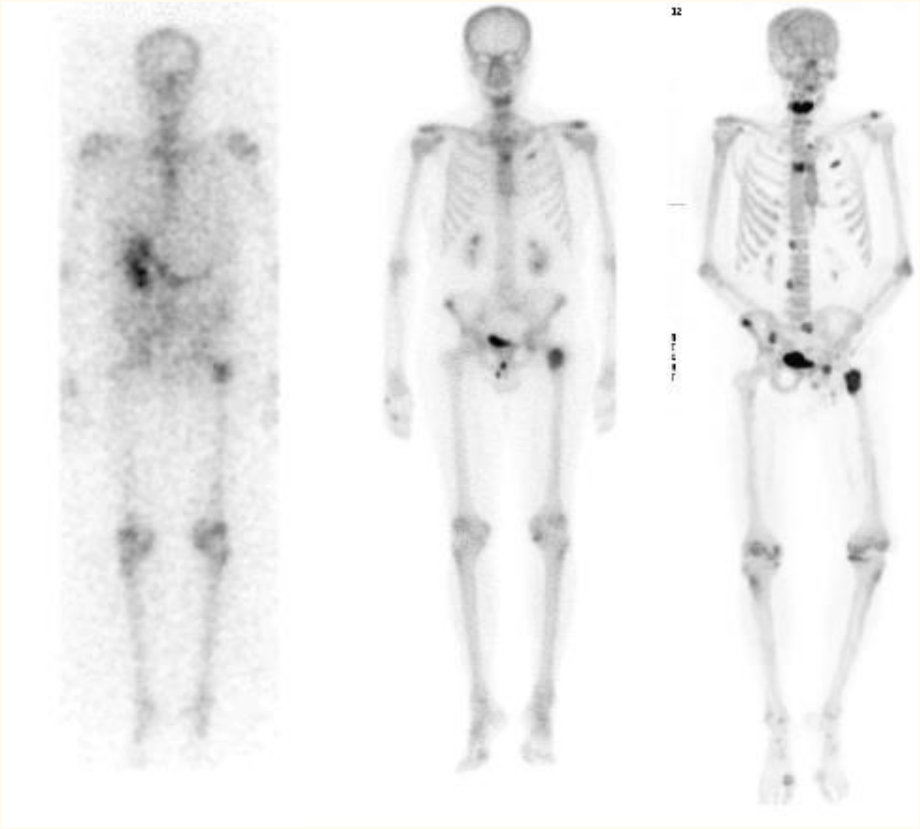
WP2: In-vivo activity quantification

Challenges

- 3D quantitative SPECT imaging is not well established for α-emitters, but is essential for post-treatment verification (BSSD)
- Progeny in-growth, low activities ➔ low counts, poor resolution
- Unknown accuracy, reproducibility and uncertainties
- Is it quantitatively good enough?

SPECT

^{223}Ra



$^{223}RaCl_2$ ^{99m}Tc-MDP ^{18}F-fluoride

Chittenden et al. JNM (2015); Murray et al. EJNMMI (2017)

WP2: In-vivo activity quantification

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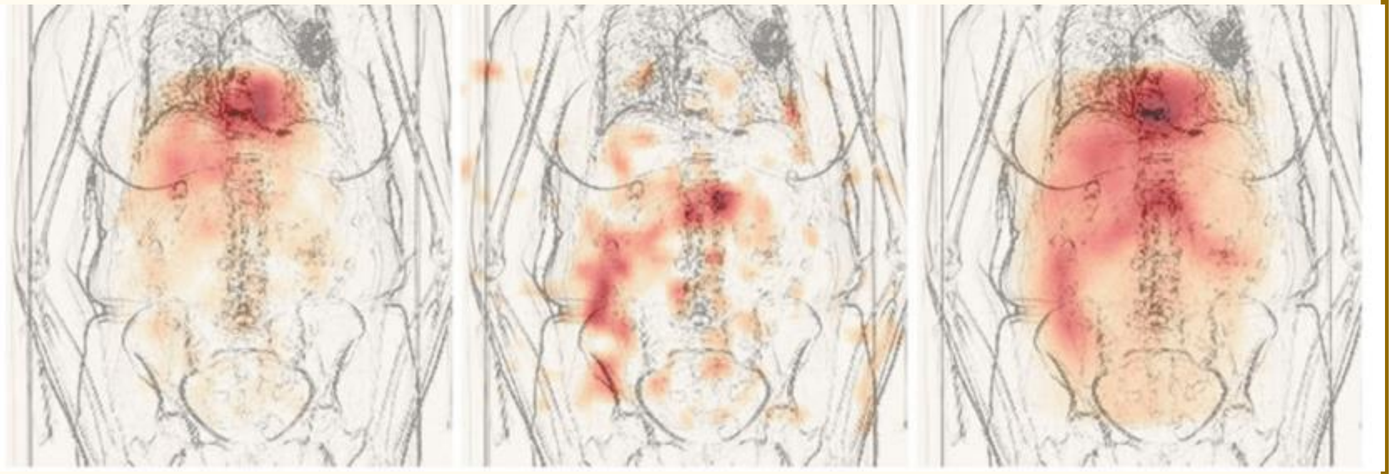
SPECT

$^{227}Th/^{223}Ra$

- A sum of all windows is useful to improve statistics, but cannot alone differentiate ^{227}Th from ^{223}Ra.



Larsson E, Brolin G, Cleton A, et al. Cancer Biother Radiopharm. 2020 Sep;35(7):540-548

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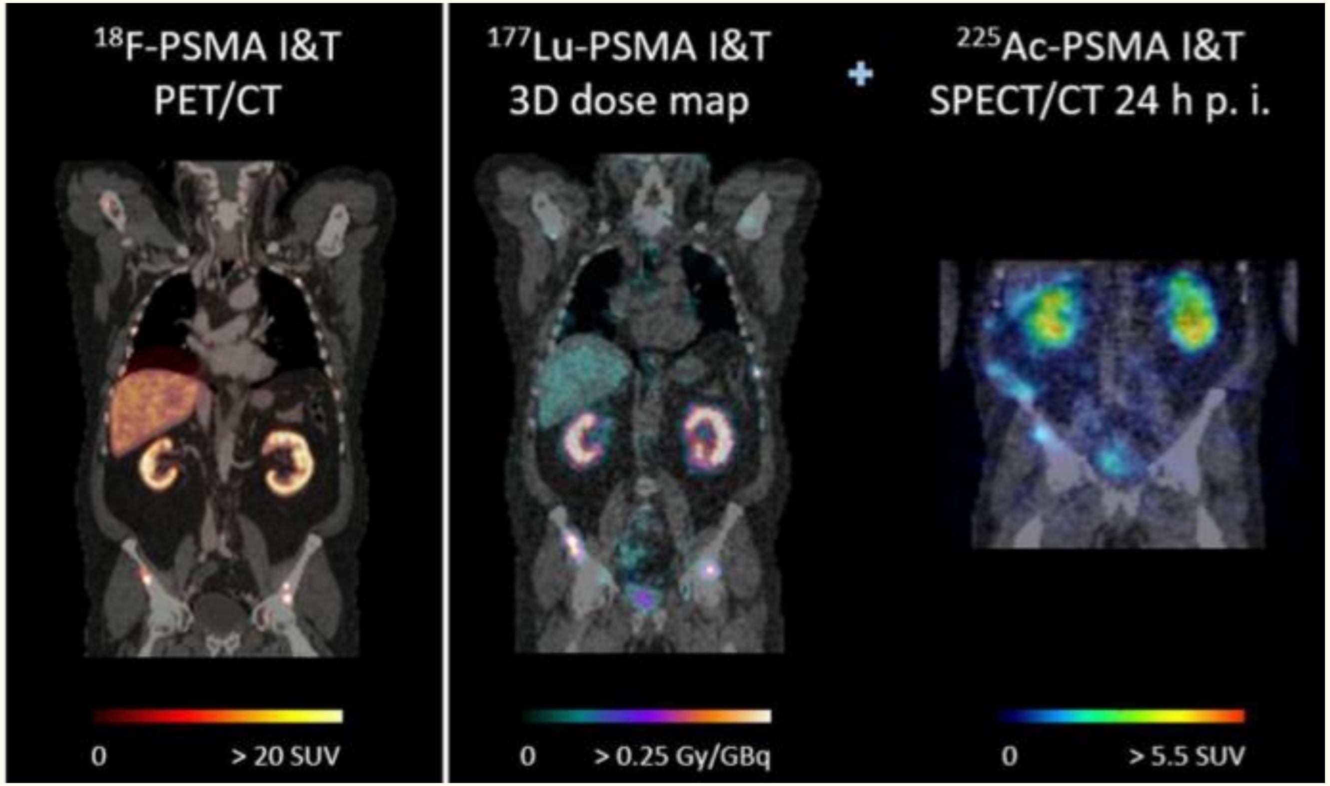
SPECT

^{225}Ac



Gosewisch *et al.* EJNNMI (2021)

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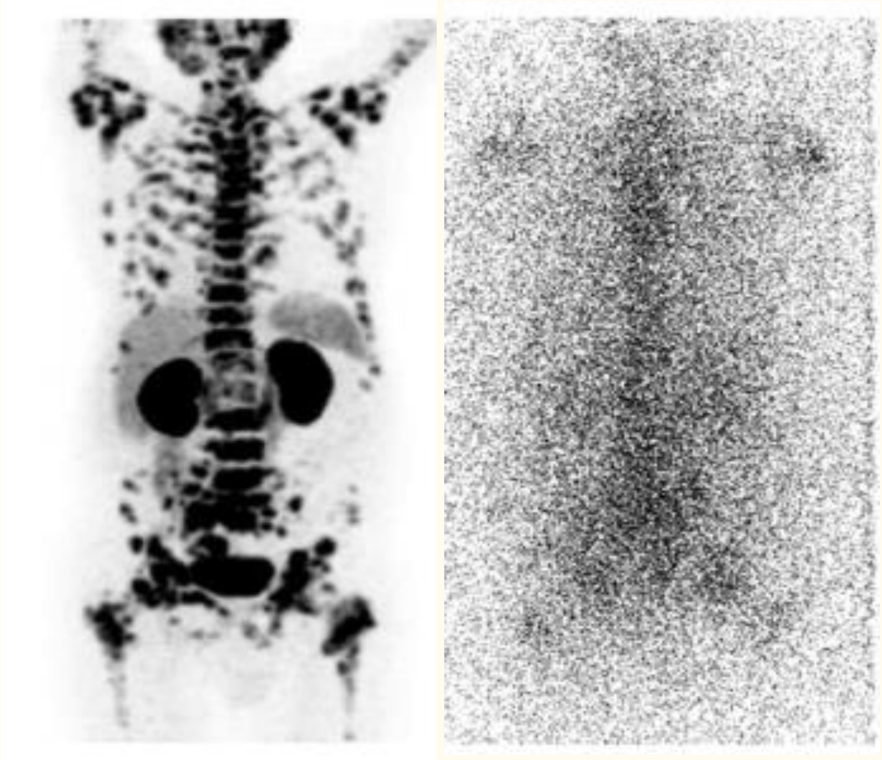
SPECT

^{225}Ac

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



Kratochwil *et al*, JNM (2016)

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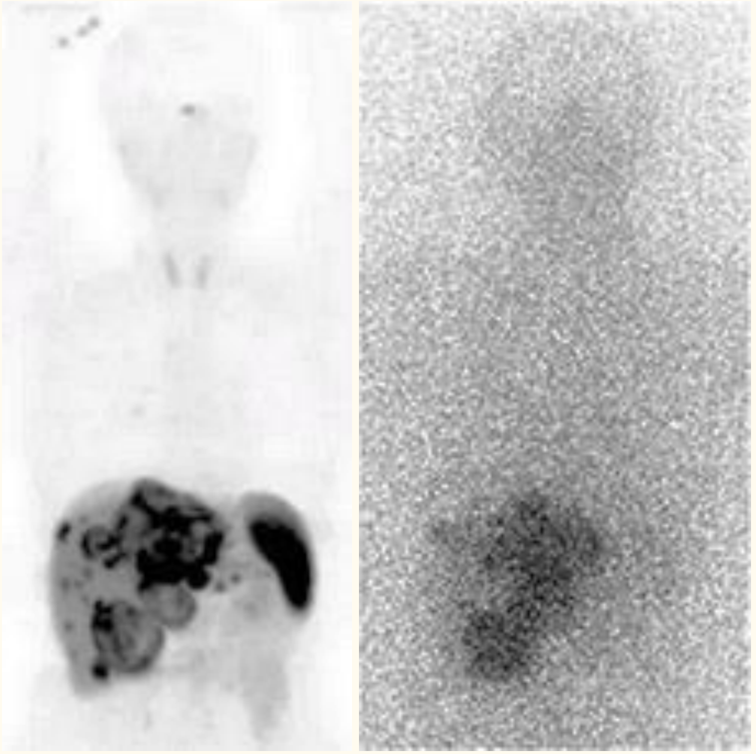
SPECT

^{213}Bi

^{68}Ga-DOTATOC ^{213}Bi-DOTATOC



Kratochwil et al, EJNMMI (2014) 41,2106-19

^{213}Bi-DOTA-SP co-injected with ^{68}Ga-DOTA-SP to assess biodistribution

Krolicki L et al, EJNMMI (2019) 46,614-22

WP2: In-vivo activity quantification
Challenges

- 3D quantitative SPECT imaging is not well established for α-emitters, but is essential for post-treatment verification (BSSD)
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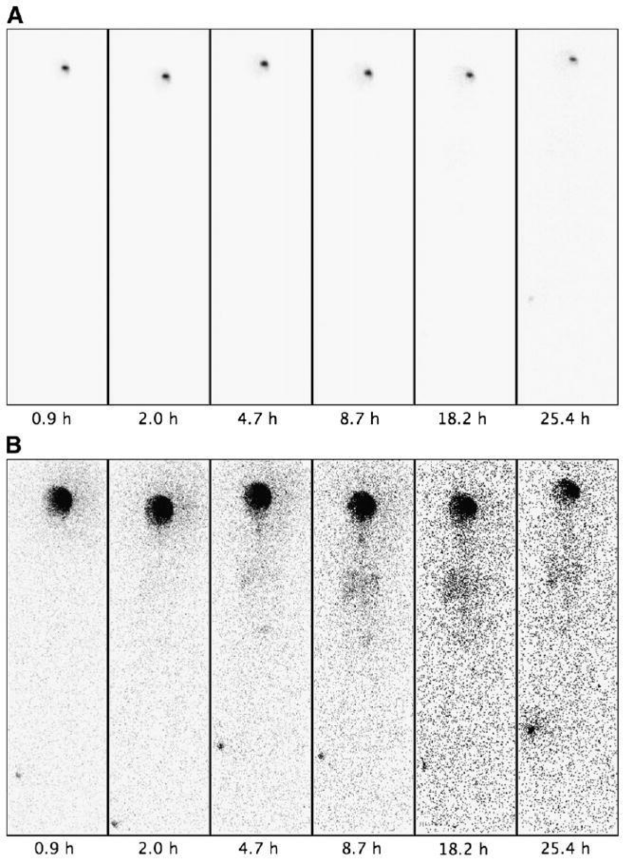
SPECT

^{211}At



^{211}At RIT for brain cancer

Loco-regional administration into the surgically created resection cavity

Zalutski M et al J Nucl Med (2008) 49:30-8

WP2: In-vivo activity quantification

Challenges

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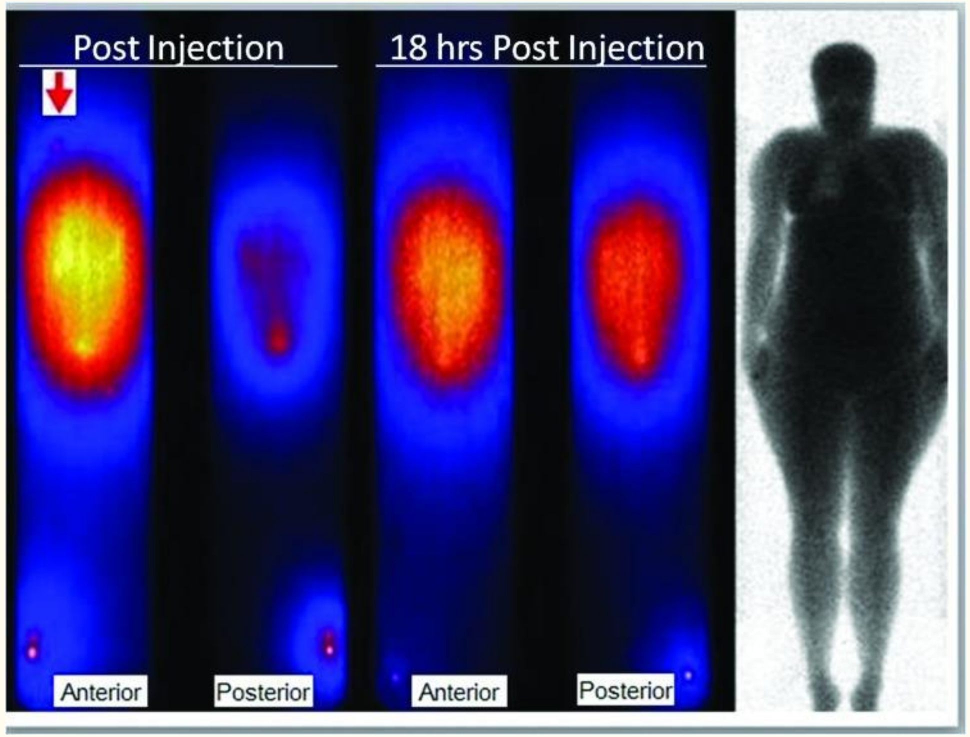
SPECT

^{212}Pb

^{212}Pb/^{212}Bi RIT targeting HER-2 positive cancers in the abdominal cavity



Meredith et al, Cancer Biother Radiopharm (2014) 29:12-7

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Challenges

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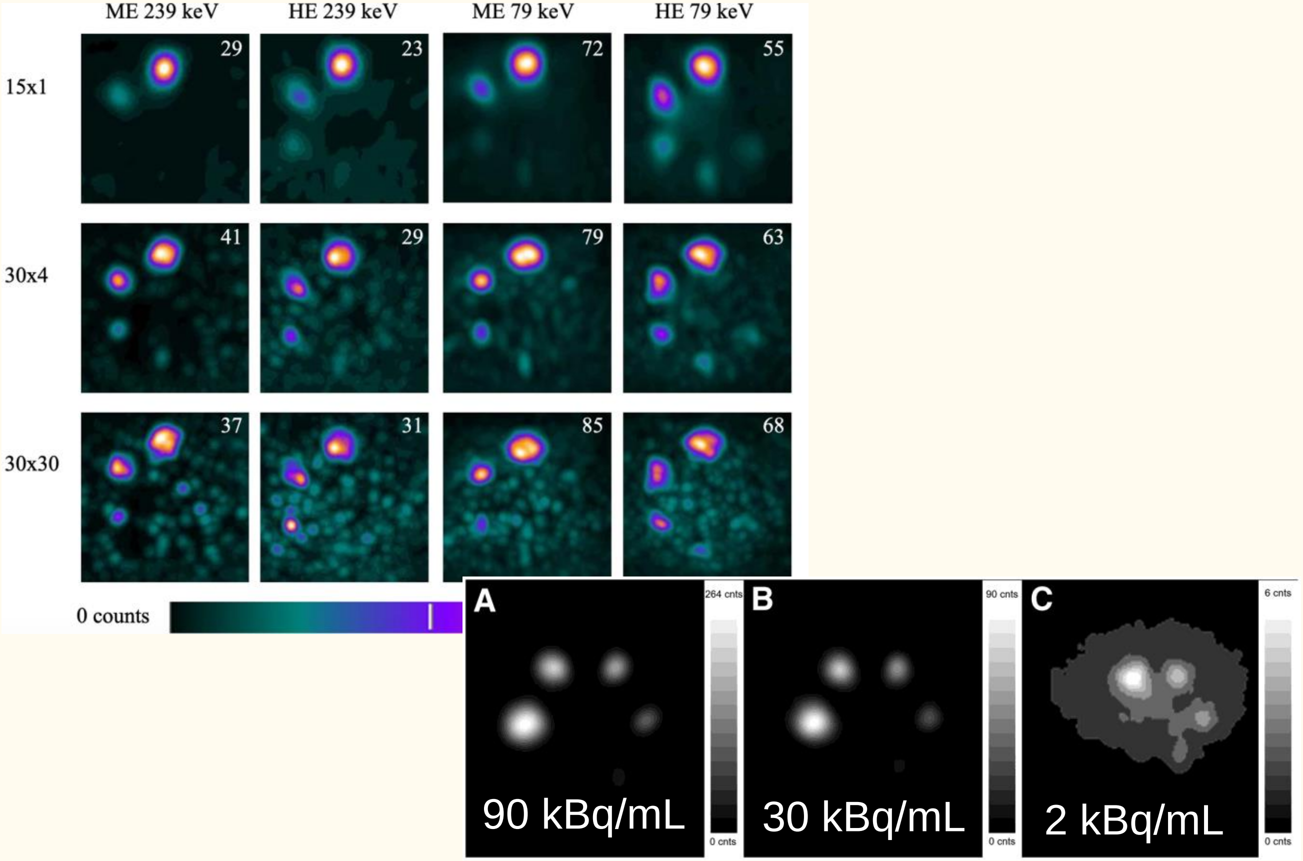
SPECT

$^{224}Ra/^{212}Pb$

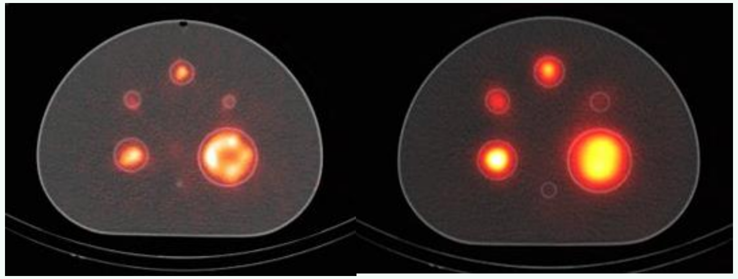


Kvassheim *et al.*, EJNMI Phys (2022), Mikalsen *et al*. JNM (2023)

WP2: In-vivo activity quantification

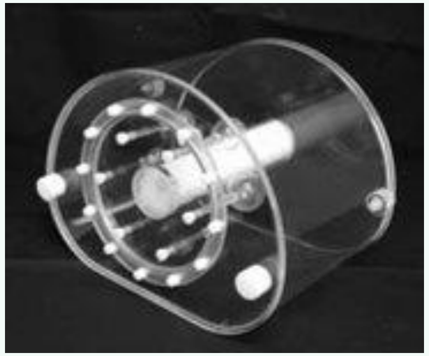
Beyond the state of the art

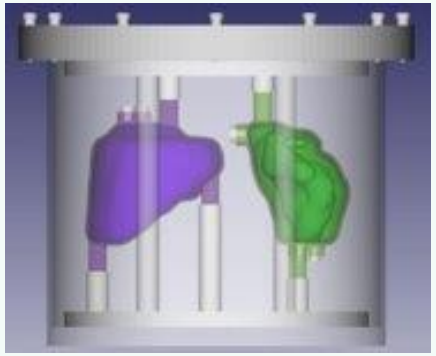
- Assess feasibility/practicality of QSPECT for α-emitters (calibration, limits of detectability, quality control)
  - ^{225}Ac
  - ^{212}Pb
  - ^{211}At



- Improve α-QSPECT with advanced processing techniques:
  - *In-silico models for image optimisation and generation of ground truth reference data*
  - *Reconstruction algorithms*

- Organise an international multi-centre comparison exercise of α-QSPECT imaging to:
  - assess accuracy, reproducibility and uncertainties of activity quantification
  - Include major manufacturers (GE, Siemens & Mediso)
  - propose guidance for harmonisation





AlphaMet: Technical Work Packages

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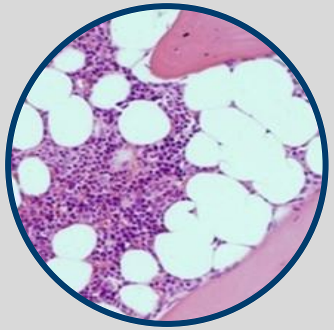
WP1
Standards

WP2
Activity

WP3
Absorbed dose



WP4
Bone marrow

End-to-end metrology

Standards (^{225}Ac, ^{212}Pb, ^{211}At)

Measurement capabilities of end-users?

QI of alpha emitters

Accuracy, reproducibility, uncertainties?

Uncertainty analysis in biokinetic modelling

Macro to micro-dosimetry

Quantitative morphological imaging of the bone marrow (DECT & MRI)

WP3: Absorbed dose quantification

Challenges

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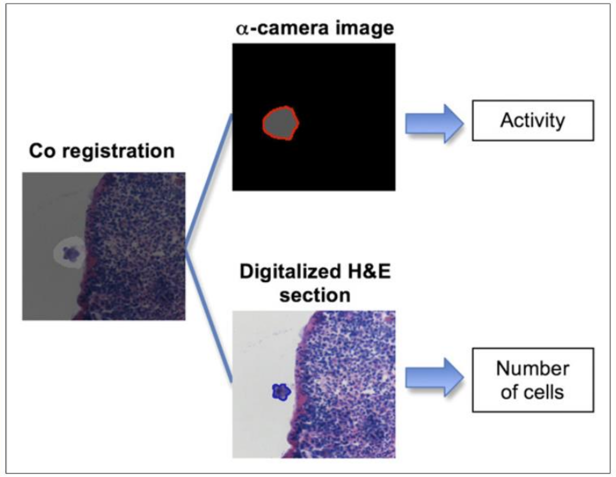
- α particles have short range and high energy (100 keV/µm) ➔ need microscopic uptake distribution (uncertainties of 75% reported by Chouin *et al.*)

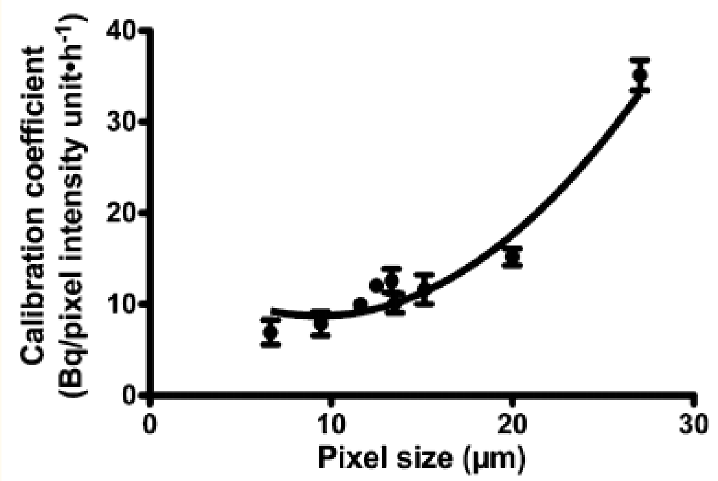
- Heterogenous distributions, complex decay schemes, in-growth, separations of progeny… ➔ routine clinical macro-dosimetry methods are not applicable

    - Murray *et al.* (100 kBq/kg $^{223}RaCl_2$): Median 4.1 Gy (0.6 – 44.1 Gy)

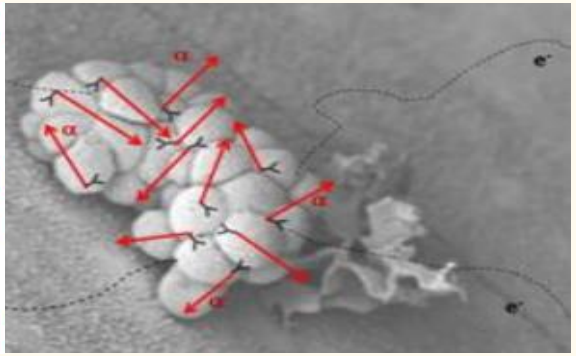
    - Pacilio *et al.* (50 kBq/kg $^{223}RaCl_2$): Mean 0.7 Gy (0.2 – 1.9 Gy) No daughters included

- What is the impact of macro vs micro dosimetry?





Chouin *et al.*, JNM (2013) 54:1347–53

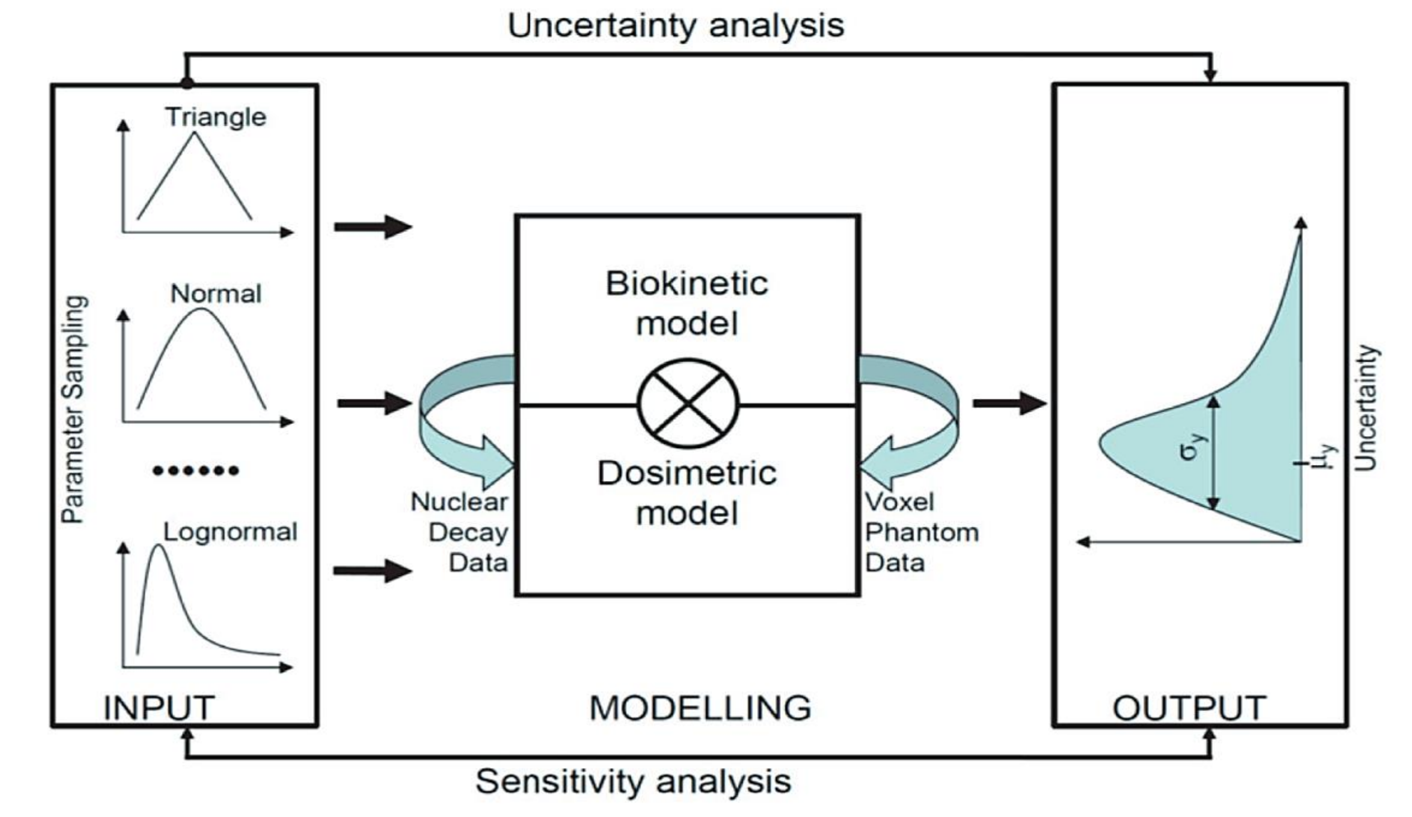


Elgqvist et al. Frontiers in Oncology (2013) 3:324

WP3: Absorbed dose quantification

Beyond the state of the art

- Provide recommendations to improve *ex-vivo* autoradiography for the quantification of activity
- Quantification of uncertainties in pharmacokinetic modelling (using existing data for ^{211}At-mAb) ➔ sensitivity analysis
- Investigate the impact of macro- to micro-dosimetry ➔ guidance on end-to-end metrology: from activity to absorbed dose quantification



Li. Japanese J Health Physics (2018) 53:72-99

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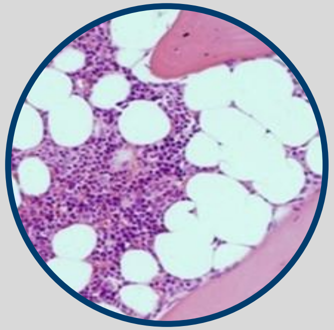
WP1
Standards

WP2
Activity

WP3
Absorbed dose



WP4
Bone marrow

End-to-end metrology

WP1:

Standards (^{225}Ac, ^{212}Pb, ^{211}At)

Measurement capabilities of end-users

WP2:

QI of alpha emitters

Accuracy, reproducibility, uncertainties?

WP3:

Uncertainty analysis in biokinetic modelling

Macro to micro-dosimetry

WP4:

Quantitative morphological imaging of the bone marrow (DECT & MRI)

WP4: Bone marrow morphological imaging

Challenges

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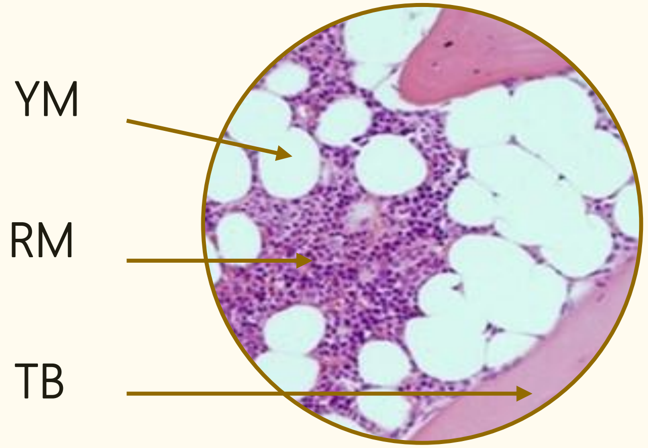
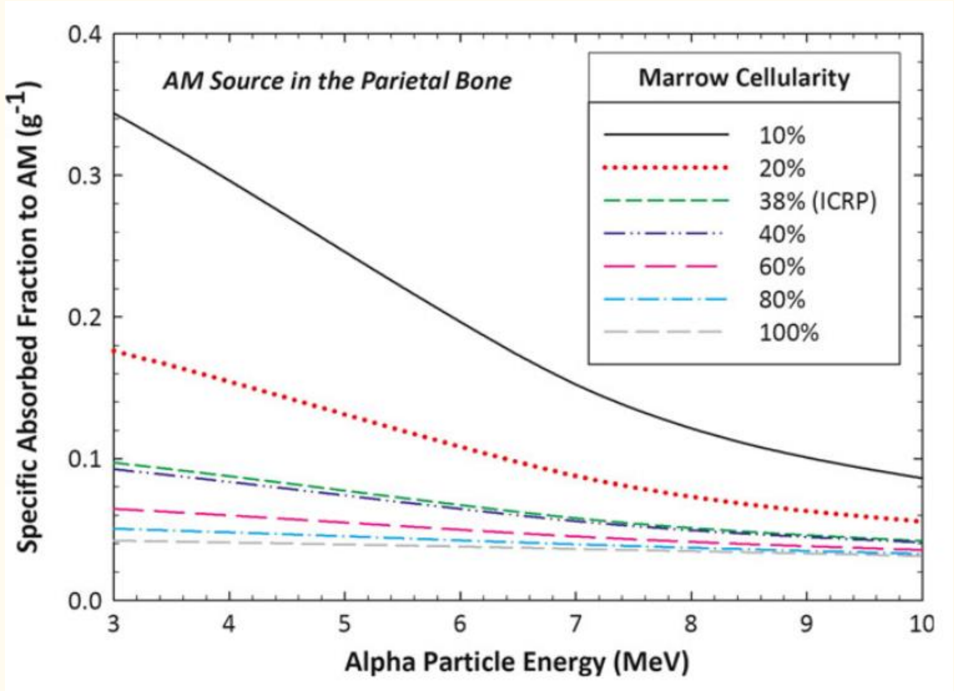
- Red marrow (RM) is the most radiosensitive tissue ➔ often limits administered activity
- Spongiosa = Red bone marrow (RM) + yellow marrow (YM) + trabeculae (TB)
- Composition changes with patient age and bone site ➔ not currently used



Clear need for patient-specific RM dosimetry

- ICRP reference models based on simplistic skeletal models
- Errors in dose factors can exceed 200-300% for self irradiation active marrow factors

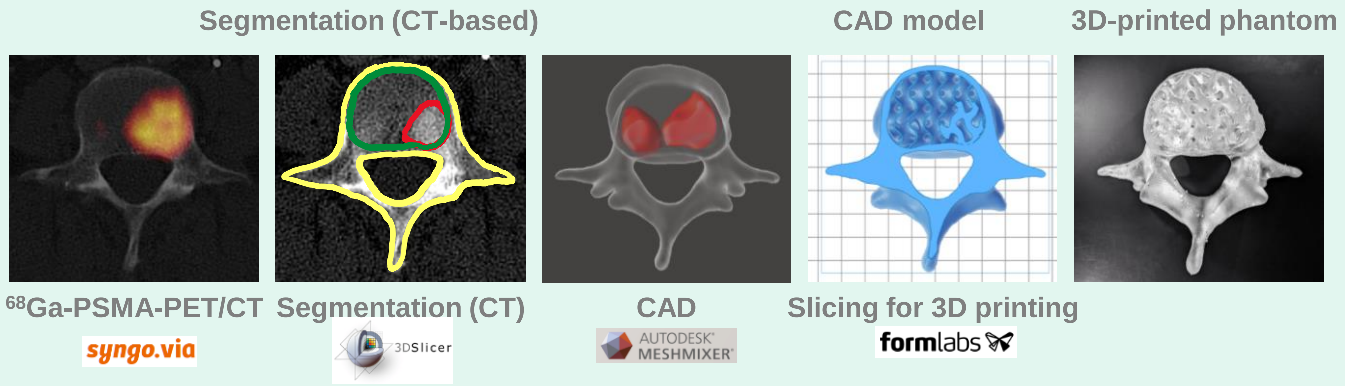


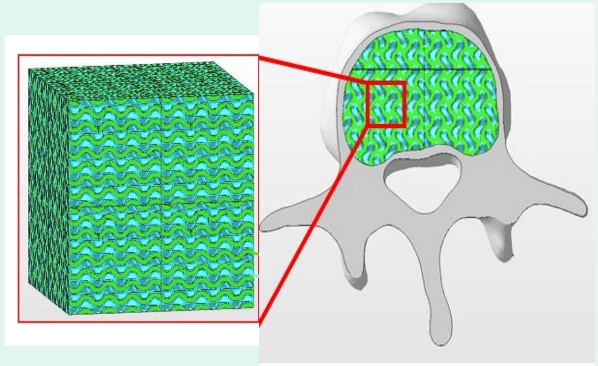
Geyer et al. Med. Phys. 44 (1) (2017)

WP4: Bone marrow morphological imaging

Beyond the state of the art

- **Design/manufacturing of a tailor-made fillable bone site phantom**
- **Optimise a protocol for morphological MR and DECT imaging to quantify the spongiosa composition (uncertainty budgets)**
- Assess the imaging-based error in RM absorbed doses
- Investigate the influence of the geometry of bone metastases on absorbed doses to the red marrow in bone sites





Need realistic densities

Used in the WP2 imaging intercomparison

WP5: Creating impact

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Results and Outputs → Outcomes → Impacts

Strong stakeholder support through letters of support

How can YOU get involved?

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- Follow project website www.alphametproject.com and LinkedIn page
  - Contact us: Coordinator (jan.rusnak@cmi.cz), Impact WP leader (ana.denisbacelar@npl.co.uk)
- Become an official collaborator:
  - Sign-up to participate in the research
  - Gives access to follow project meetings and on-going research
  - Easy (sign agreement with coordinator) & free ☺
- Join our stakeholder workshops:
  - 1st @ at BIPM
  - 2nd (TBC, Summer 2025) & 3rd (TBC, Sep-2026)
- Coming up in September 2024:
  - Survey on activity measurements, imaging and dosimetry for alpha emitters

Thank you for listening

A.M. Denis-Bacelar, C. Bobin, M. Koole, S. Palm, J. Tran-Gia, C. Bailat, R. Broda, M. Capogni, S.M. Collins, D. Deidda, A. Delker, M.T. Duran Ramiro, A.J. Fenwick, K. Ferreira, F. Haddad, F. Juget, M. Kellet, M. Lassmann, W.B. Li, P. Mínguez Gabiña, D. Panciera, M. Roteta Ibarra, M. Salas Ramirez, C. Saldarriaga Vargas, J. Sochorova, A.P. Robinson, J. Scuffham, J. Solc, L. Struelens, A.L. Thiesen, T. Ziemek, S. Ziegler, **J. Rusnak**

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