ETRAIN

Establishing Traceability Routes in Nuclear Medicine

Creating traceability infrastructure for Nuclear Medicine

Harmonising Nuclear Medicine measurements across Europe

Drivers and needs

- 40 million nuclear medicine (NM) procedures are performed each year ► Demand for radioisotopes is increasing by ~5% annually
- The global NM market is anticipated to grow to 37.6 billion € by 2032
- Number of NM treatment procedures since 2008 increased by 55 %
- Uncertainties are unknown in administered activities and imaging ► Lack of traceability in NM might lead to inaccurate activities being administered contravening EC Directive 2013/59/EURATOM

Scientific and technical excellence

WP1: Establishment of traceability routes

Current state of the art

- Not all NMI/DIs in Europe maintain primary standards of radioactivity
- Access to radioactivity standards in hospitals varies across Europe
- Clinical users reliant on non-traceable manufacturer supplied settings
- Low engagement between end-users and metrology communities.

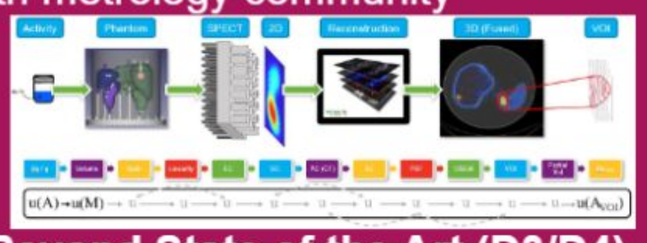
Beyond state of the Art (D1/D2)

- ✓ Establish traceability routes in partner countries for important radionuclides
- ✓ Create framework through guidance to expand networks internationally
- ✓ Engage with user community to facilitate uptake

WP2: Assessing Uncertainty

Current state of the art

- No uncertainties = no traceability
- Unknown accuracy in administrations
- Unknown accuracy in activities derived from images and dosimetry calculations
- Low engagement of clinical community with metrology community



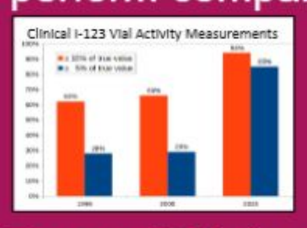
Beyond State of the Art (D3/D4)

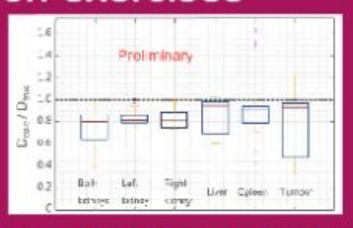
- ✓ Enable traceability routes to be created by incorporating uncertainties
- ✓ Determine current capability and highlight areas requiring improvement
- ✓ Engage with community to ensure uncertainties are a routine part of measurement

WP3: Validation of effectiveness

Current state of the art

- Comparison exercises in nuclear medicine not performed routinely
- Measurement capability in hospitals largely unknown across Europe
- Minimal guidance available on how to perform comparison exercises





Beyond State of the Art (D5/D6/D7)

- ✓ Perform comparisons to assess effectiveness of new calibration routes
- ✓ Create guidance to improve quality and quantity of comparison exercises performed in nuclear medicine.
- ✓ Deliver training and advice to end users on importance of traceability
- ✓ Enable future expansion of traceability

WP4: Creating Impact

Stakeholder and Industry Support

Seven technical deliverables

Communication and dissemination:

- Website, Newsletters, Social Media
- Stakeholder Committee, 4 workshops
- Engagement with societies & conferences
- Three guidance documents, at least two publications & training material

Exploitation:

- Uptake of outputs by hospitals, equipment manufacturers, radiopharmaceutical industry…

Upskilling the workforce through training

Outcomes for Industry & others

- New calibration services available
- Protocols for establishing traceability
- Guidance on uncertainty estimation
- Facilitate CMC claims

Standards and Compliance:

- Support compliance with regulations (EC Directives 2013/59/EURATOM, 2001/83/EC and 2001/20/EC)
- International uptake of outputs by IAEA, EANM, EFOMP & NM Societies

Establish new networks & collaborations

Long Term Impact

Economic/technical:

- New calibration services from NMI/DIs creating traceability networks improving capability & harmonisation across Europe
- Improved accuracy of therapeutic and diagnostic administrations
- enabling pooling of data from multicentre clinical trials in NM

Social:

- Accurate administrations and dosimetry in NM, improving the patient pathway

WP5: Management / Coordination / Consortium

- **9 NMI/DIs:** NPL (Coordinator, UK), VSL (WP1 lead, Netherlands), STUK (WP2 lead, Finland), CMI (WP3 lead, Czechia), FTMC (Lithuania), IST (Portugal), SSM (Sweden), CHUV, METAS (Switzerland).
- **5 clinical beneficiaries:** Lund (WP4 lead, Sweden), HUS (Finland), VUHSK (Lithuania), KS (Sweden), RSFT (UK).