# EU4H-2023-PJ-05 - Call for proposals to support the implementation of the strategic agenda for medical ionising radiation applications (SAMIRA) – Organisation of clinical audit campaigns as a tool to improve quality and safety of medical applications of ionising radiation

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# Policy context – SAMIRA Action Plan

### Security of supply of medical radioisotopes

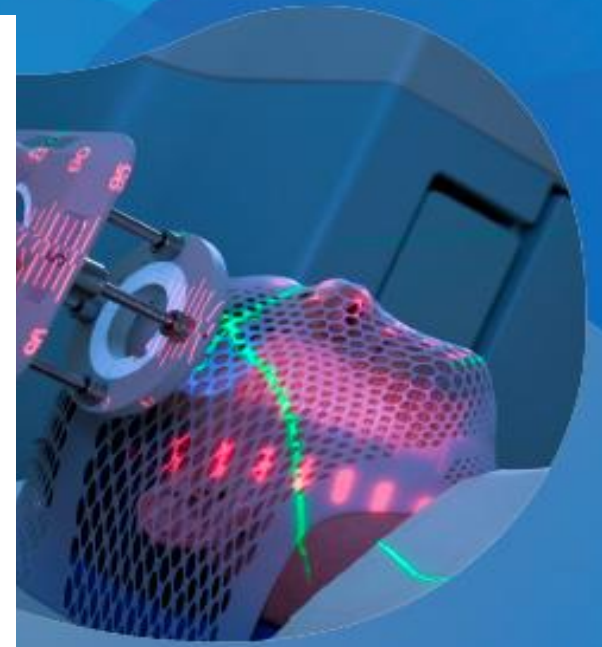
- Launch of the European Radioisotope Valley Initiative (ERVI)
- Secure supply of source materials for production of radioisotopes
- Support to long-term sustainability of radioisotope production in Europe

### Quality and safety of medical ionising radiation applications

- Launch of the European Initiative on Quality and Safety of medical applications
- Improvements to workforce availability, education and training
- Support for equal access to modern technology and interventions

### Innovation and technological development

- Research roadmap for medical applications on ionising radiation technology
- Joint Health Technology Assessment of technologies and interventions involving ionising radiation



European Commission

# Policy context - SAMIRA Steering Group on Quality and Safety

**Steering Group on Quality and Safety**
**Common European platform for Member State Health and Radiation Protection authorities**
**25 Member States + Norway**

**Basic Safety Standards Directive 2013/59/Euratom requirements**

- **Data collection**
  - Patient dose, Incidents, KPIs
- **Guidance and evidence**
  - Justification, Optimisation, Clinical Audit
- **Regulatory co-ordination**
  - Pharma, Medical devices
  - e-Health
- **Workforce availability, E&T**
- **Access to equipment and procedures**

**SGQS topical WGs:**
- **WG CA**
- **WG KPIs**
- **WG DRLs**

**Guidance and recommendations**

**Support actions**

**Sharing of good practices**

**MS implementation and feedback**

EU general budget

EU4Health programme

Euratom R&T programme

European Commission

# Policy context - SAMIRA Steering Group on Quality and Safety

The Basic Safety Standards Directive defines clinical audit as

"*a systematic examination or review of medical radiological procedures which seeks to improve the quality and outcome of patient care through structured review, whereby medical radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, with modification of practices, where appropriate, and the application of new standards if necessary*"

BSSD Article 58(e) requires Member States to carry out clinical audits in accordance with national procedures.

# Policy context - SAMIRA Steering Group on Quality and Safety


**SGQS**

- Draws conclusions from the QuADRANT project
- Supports the implementation of QuADRANT recommendations in MS

**Work area**

Clinical Audit

**SGQS WG on clinical audit**

**Position paper** of the SGQS on clinical audit (adopted 13/06/23)

Support for **clinical audit campaigns** in EU4Health WP23

**MS implementation and feedback**

**SGQS Position paper on Clinical Audit** = **Recommendations from the SGQS to MS authorities**

- recognises clinical audit as an important tool for healthcare quality and safety,
- provides recommendations for establishing a national framework for clinical audit,
- considers the role of regulatory control, accreditation and certification, enablers and management support and patient involvement in relation to clinical audit

European Commission

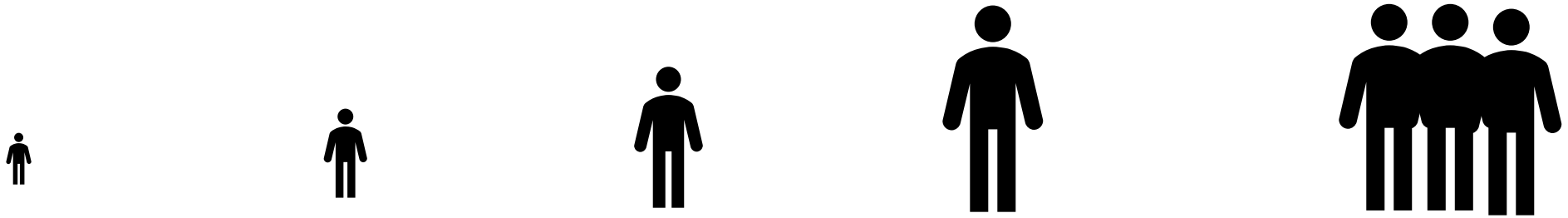
# Clinical Audit campaigns in Member States

**Objectives:**

- Pilot clinical audit campaigns in Member States in diagnostic and interventional radiology, radiotherapy and nuclear medicine by identifying and bringing together relevant actors and resources.
- Campaigns should be implemented in coordination with the health authorities and take into account the specificities of national health systems.
- Campaigns should seek to improve justification of radiological imaging and the implementation of the optimisation principle.
- Proposals should include considerations and activities to scale-up pilot outcomes into the broader health system practice of MS.

# Clinical Audit campaigns in Member States

→ Up to 4 proposals of different sizes will be accepted
→ Total budget 1 500 000 €



Single (large) departement or hospital

Hospital trust

Region

Single Member State

Several Member States

Priority will be given to proposals covering several types of medical practice in several Member States and also to different practices within different regions of a Member State.

# Clinical Audit campaigns in Member States

**Activities funded under this project include:**

- Networking
- Communication
- Coordination
- Planning
- Recruiting
- Training
- Auditing
- Reporting
- Dissemination activities

**Activities also include the identification of documents:**

- Clinical audit guidelines
- Audit templates
- Agreed standards for good medical practice

**or the elaboration of new documents** in areas of under-developed CA practice

**and the development and/or use of web-based tools** to share resources and boost discussions about CA (e.g. EU Health Policy Platform)

# Expected impact

- Improve overall Quality and Safety of radiological medical procedures
- Better implementation of the BSSD requirements with regard to clinical audit
- Serve as a reference action to establish a permanent clinical audit mechanism in Member States
- Contribute to the development of the professional skills of the auditors and of the audited professionals
- Foster inter-disciplinary and multi-professional relationships
- Contribute to the developement of leadership in this area
- Strengthen structures involved in hospital accreditation or individuals involved in certification schemes

# Special requirements

| | |
|---|---|
| **Type of applicants targeted** | Academia (e.g., public health institutes) and education establishments, research institutes, hospitals, professional societies, competent authorities and established networks in the field. |
| **Specific eligibility and selection criteria applicable to the consortium composition** | Applications may be submitted either by a single applicant or a consortium.)<br>In both cases (single applicants or consortium) the proposal must include one eligible applicant with expertise in at least one of the following medical specialties: radiology, radiotherapy, nuclear medicine, other medical specialties using ionising radiation.<br>This needs to be clearly highlighted in the proposal. |
| **Non-eligible activities** | N.A. |
| **Other topic requirements** | A priority will be given to proposals covering several types of medical practice in several Member States or different practices within different regions of a Member State. Proposals should include considerations and activities to scale up pilot outcomes into the broader health system practice of Member State(s). |

# Timetable and deadlines

| **Timetable and deadlines (indicative)** | |
|---|---|
| Call opening: | 15 June 2023 |
| Deadline for submission: | 17 October 2023 – 17:00:00 CET (Brussels) |
| Evaluation: | November-December 2023 |
| Information on evaluation results: | January 2024 |
| GA signature: | July 2024 |