

Shaping the future for improved quality and safety in the medical use of ionizing radiation

PrISMA - a preparatory Joint Action (JA)

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Preparatory activities for
Implementation of quality and
Safety of
Medical ionizing radiation
Applications

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Agenda

1. EU's initiative on medical ionising radiation applications (SAMIRA)
2. EU4Health programme
3. PrISMA
4. Way forward and future SAMIRA Joint Action



SAMIRA

- [SAMIRA](#) = **S**trategic **A**genda for **M**edical **I**onising **R**adiation **A**pplication
- DG-ENER's contribution to the European Cancer Plan; [Europe's Beating Cancer Plan](#)
- [SAMIRA Action Plan](#) is supporting health care services that are:
 - safe
 - reliable
 - of good quality



Europe's Beating Cancer Plan

Communication from the commission to the European Parliament and the Council

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Prioritized areas in SAMIRA



- Secure supply of medical radioisotopes (ERVI)
- Facilitating innovation and technological development of medical ionising radiation application
- Improving quality and safety in medical ionising radiation application



SAMIRA steering group - SGQS



- Health authorities and radiation protection authorities
- Support implementation of requirements for radiation protection onto the national health policies, health systems and in clinical practise.



SAMIRA roadmap



Patient dose

- Recommendation for collect, store and analyse patient dose data
- Improve quality of data



Incidents

- Establish and disseminate guidance to support efficient incidents reporting and use of reported data



Justification

- Develop the use of the justification principle
- Promote the availability and use of referral guidelines and clinical decision support systems



Optimisation

- Develop the use of the optimisation principle
- Support the dissemination of existing reference documents on DRLs



Clinical audits

- Support clinical audit implementation



Regulatory coordination

- Radiation protection
- Radiopharmaceuticals
- Medical devices



Improved workforce availability, education and training

- Monitor workforce availability
- Draft guidelines on staffing and education/training



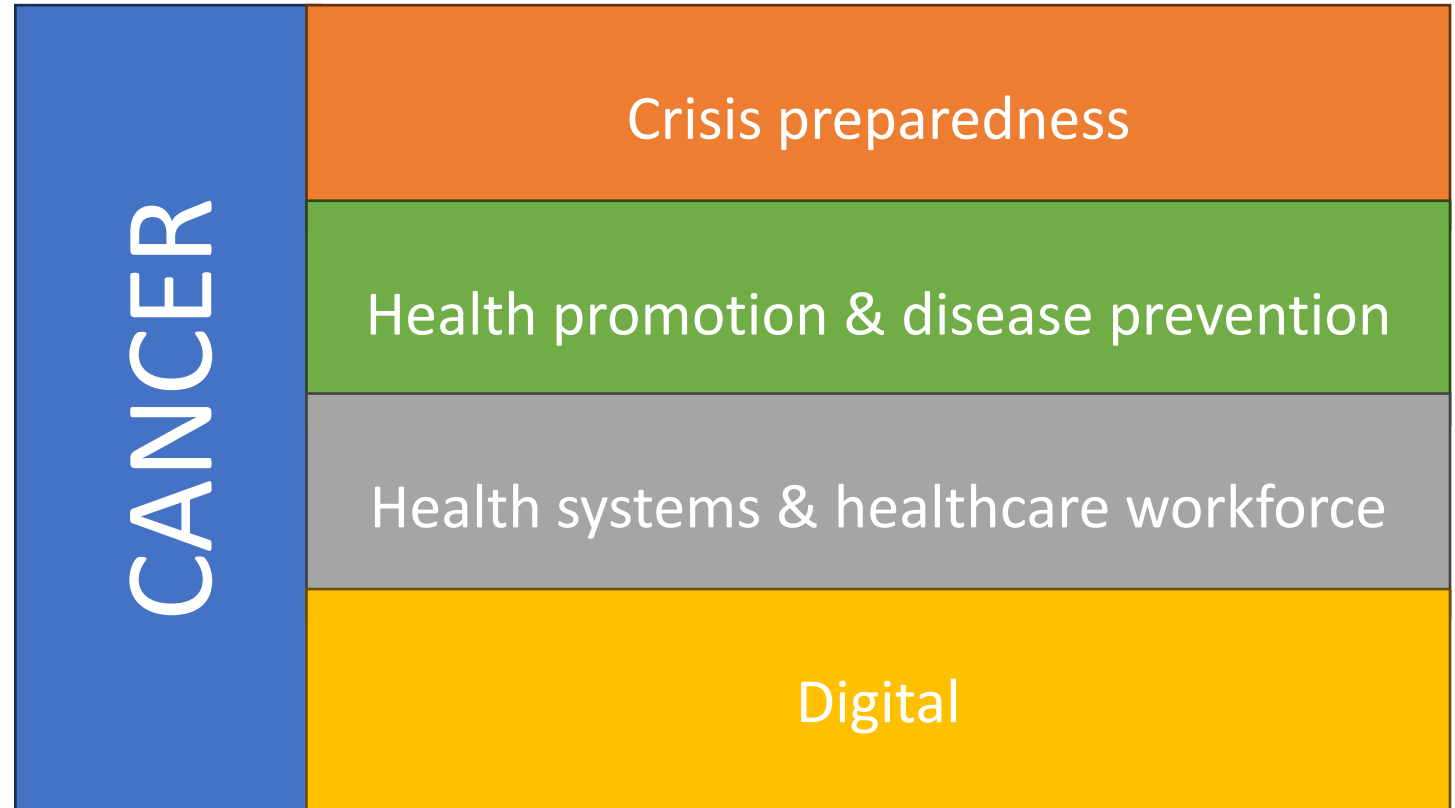
Sharing of practises

- Support the identification and promoting of good practices identified in MS



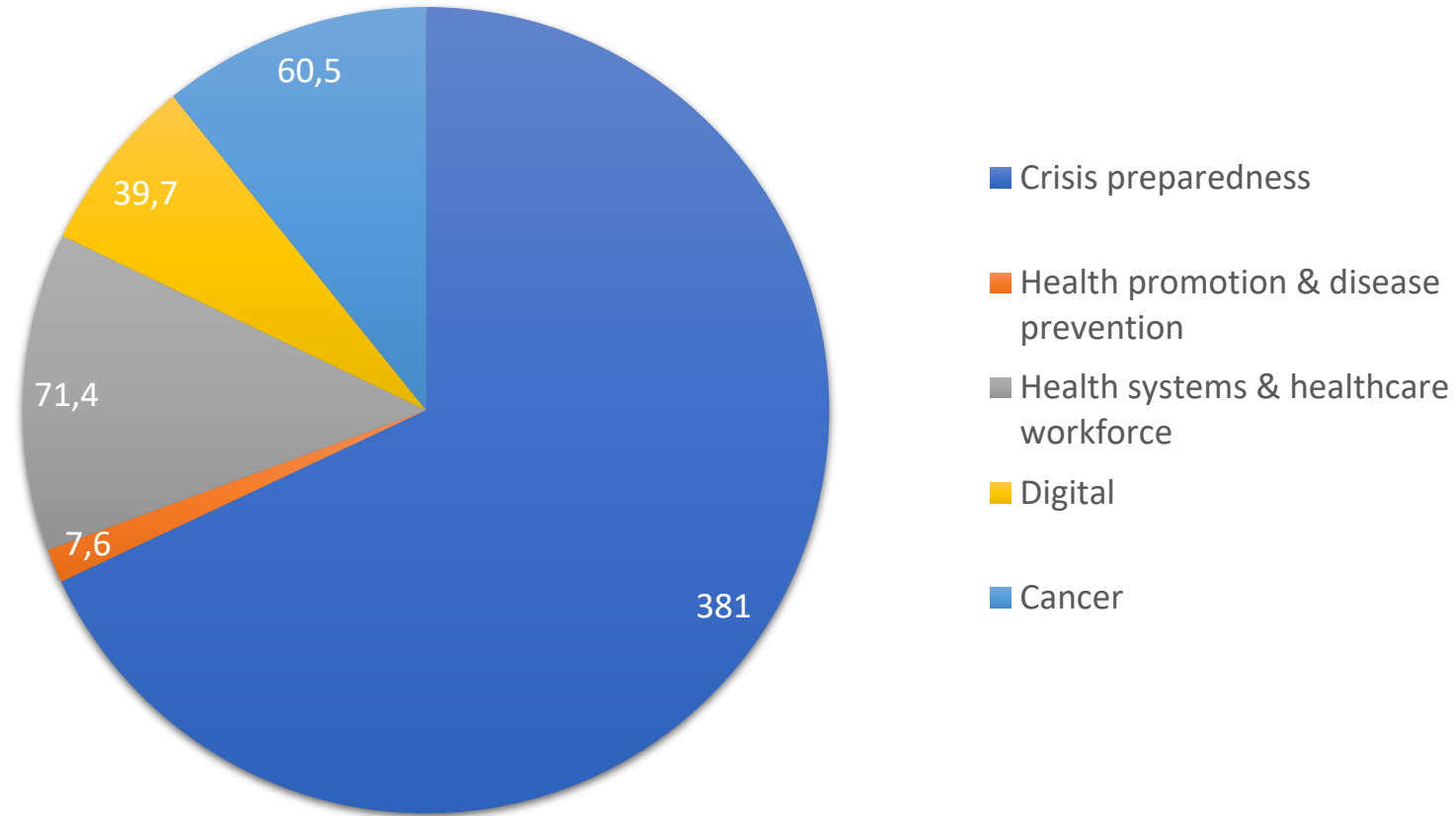
EU4Health Programme

- Period 2021-2027
- Total €4.4 billions
- 33 eligible countries (all EU MS + associated countries)
- Grants/contracts
 - Direct grants/Joint Actions
 - Tender and procurements
 - Open grants
- Main goals
 - Strengthen EU's health union
 - Contribute to EU's health priorities



EU4Health Work programme 2025

Allocated budget in million € for different categories



Joint Actions

- Cooperation between authorities
- Participation:
 - Competent Authority (CA)
 - Affiliated Entity (AE)
 - Associated Partner (AP)
- Funding 60% or 80%
 - Depending on defined criteria
 - Remaining funding is covered by CA/AE themselves



Preparatory activities to support Implementation of quality and Safety of Medical ionising radiation Applications - PrISMA

Key objectives:

- 1) map the relevant actors in Member States and conduct network activities to promote future initiatives
- 2) produce a proposal for a future Joint Action in the area of quality and safety of medical applications of ionising radiation, including objectives, scope and activities.

PRISMA

PrISMA - Structure

- Duration: 18 months, from May 2024
- Budget: € 1.000.000
- Partners: 18 organisations, 12 countries
- Coordinator: Charlotte Rosenbaum, National Institute of Public Health and the Environment (RIVM), Nederland



WP1 Coordination – RIVM (NL)



WP2 Dissimination – LSMUKK (LT)/CROMPA (HR)



WP3 Evaluation – ICO (ES)/ISS (IT)



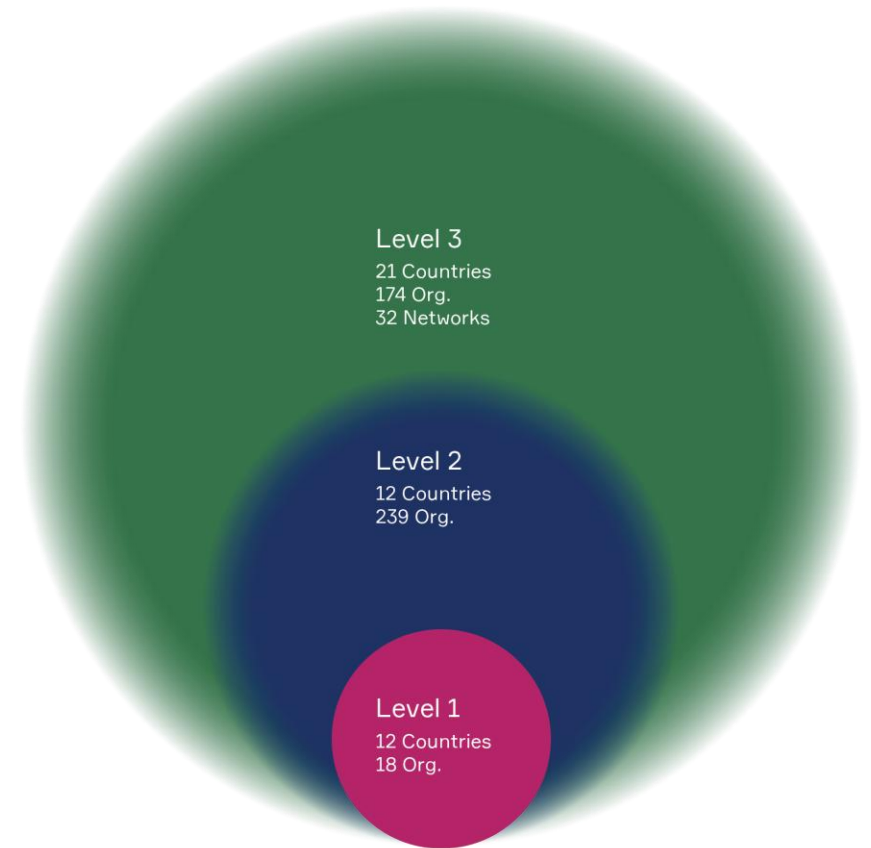
WP4 Sustainability – NCPHP (HU)/DSA(NO)



WP5 Technical workpackage – STUK (FI)/MPA(SE)

PrISMA - Activities

- Stakeholder mapping
- Defining projects for future JA
- Stakeholder workshop (>150 participants, 24 countries)



PrISMA – proposed projects for future JA

1. Strengthening & Streamlining Generic Justification in Europe
2. Individual Justification of Medical CT Procedures
3. Optimisation of Radionuclide Therapy
4. Optimisation of Radiation Protection in Paediatric Imaging
5. Optimisation of Radiation Protection in Interventional Radiology
6. Optimisation in Image Guided Radiotherapy (IGRT)
7. Diagnostic Reference Levels in NM, CT, Interventional Radiology and Radiography Procedures
8. Procedures for Recording and Monitoring Patient Exposure Data in CT, Interventional Radiology and Diagnostic NM Procedures
9. Radiation Protection During Pregnancy Related to Medical Exposure
10. Strengthening the Implementation of Incident Learning Systems
11. Effective Implementation of Clinical Audits
12. Revisiting European Clinical Image Quality Criteria for X-ray Imaging Supporting Clinical Optimisation



Future SAMIRA JA



- EU4Health 2025 [Work programme](#) is published, SAMIRA JA (pp. 43-45)
- Joint Action – Cooperation among authorities, given criteria for participation
- To participate:
 - Must be nominated by national Ministry of Health (by Oct. 16th)
 - National formalised processes, differs from country to country



Future SAMIRA JA

- EUR 11 500 000
- Based on SAMIRA Action Plan, supporting implementation of high standards for quality and safety of medical applications of ionising radiation.
- Former SAMIRA initiatives → conclusions and recommendations
- JA PrISMA → preparatory JA



Future SAMIRA JA - objectives

- **Main objectives:**

- improvements in quality and safety of medical radiological procedures in Member States by supporting the coordinated implementation of good practice, developed in the context of SAMIRA, in the national health systems.
- build on the evidence, lessons and recommendations from the SAMIRA projects and translate them into practical implementation in several countries simultaneously.
- forum to exchange good practices between Member States



Future SAMIRA JA - deliverables

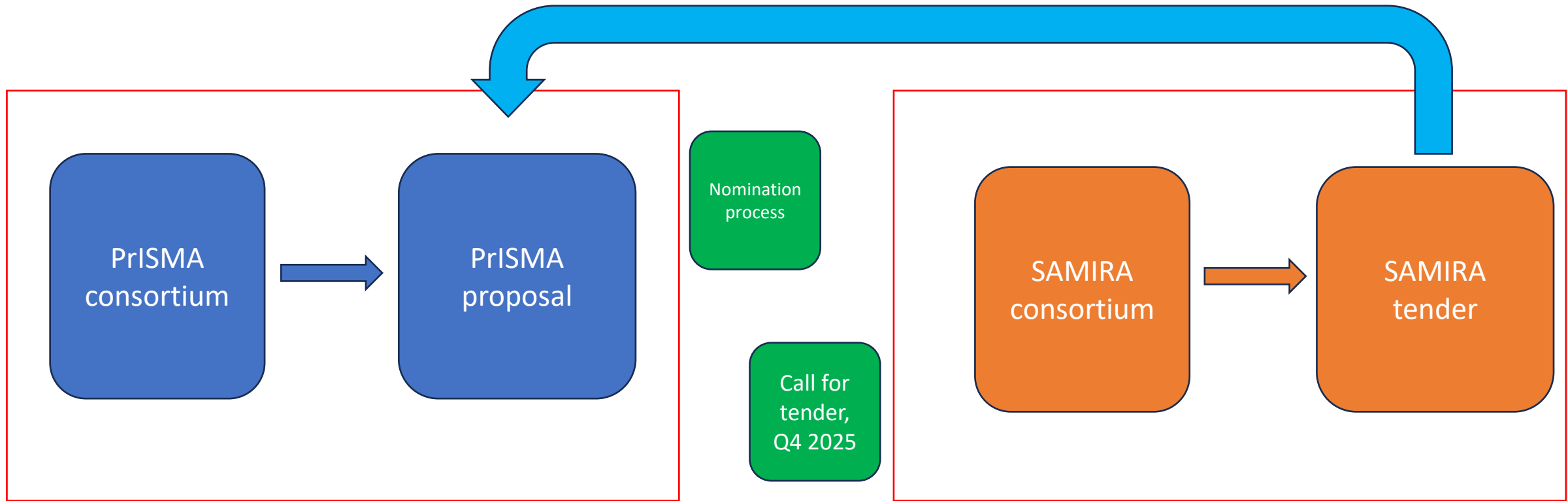


- **Mandatory deliverables/milestones:**

- best practice guidance and working procedures for clinical auditing of computed tomography (CT) referrals to improve justification of diagnostic radiology
- development of new/update of existing working procedures for incident reporting in radiotherapy, diagnostic/interventional radiology
- development of new/update of existing working procedures for recording and monitoring of patient radiation dose;
- development and dissemination of practical guidelines on optimisation of paediatric radiation protection;
- development of guidelines for optimisation of image-guided radiotherapy;
- implementation of the requirements of Council Directive 2013/59/Euratom Basic Safety Standards Directive 59 related to optimisation and dosimetry in radiopharmaceutical cancer therapy



Future SAMIRA JA



Competent authorities

Country	Organisation
Finland	Radiation and Nuclear Safety Authority
Sweden	Swedish Radiation Safety Authority Swedish Medical Products Agency
Norway	Norwegian Radiation and Nuclear Safety Authority
Denmark	Danish Health Authority
Iceland	Icelandic Radiation Safety Authority



Thank you for your attention!



Photo: Trude Dahl Jørgensen