Guiding AI in Radiology:

EUROPEAN SOCIETY OF RADIOLOGY

ESR's Implementation Recommendations for the European AI Act

The European Society of Radiology (ESR) advocates for the responsible and safe adoption of AI technologies in radiology. Our recommendations, focused on key aspects of the EU AI Act such as **transparency**, **safety**, **data governance**, and **human oversight**, aim to ensure that AI applications will deliver real, safe, and patient-focused benefits in radiology across Europe.

1. Promote AI Literacy

Promote **AI literacy** for both healthcare providers and patients to enhance understanding of AI systems, their opportunities, and risks. This includes developing a **code of conduct** for AI in medical imaging and incorporating **AI education** into medical school and residency curricula, as well as **continuous training** for current professionals.

2. Clarify High-Risk AI Classification

Clarify the **classification** of high-risk AI systems, ensuring that any AI impacting clinical decisions is properly regulated with **standardised guidelines**. ESR urges early involvement of domain experts to develop **practical guidelines** for high-risk applications, including **workflow optimisation** and **triage tools**, to ensure **patient safety** and reduce ambiguity.

3. Strengthen Data Governance for AI Reliability

High-quality data governance is crucial for **AI reliability**. ESR supports developing **standardised** data governance frameworks, aligned with **GDPR** and the **European Health Data Space (EHDS)**, to ensure datasets are **representative** of real-world diversity and geographical variability.

4. Enhance Transparency Between AI Providers and Healthcare Professionals

Mandate AI providers to ensure **transparency** in the use of AI systems, through the use of **detailed model cards** outlining training data, performance metrics, intended use, and potential limitations. This clear communication between providers and deployers is essential to **build confidence** among healthcare professionals and **prevent the misuse** of AI systems in clinical settings.

5. Ensure Human Oversight in AI Deployment

Establish **clear guidelines** to ensure that AI does not replace clinical judgment but instead augments it. Continuous professional education, appropriate AI training and re-certification programmes can mitigate risks such as **automation bias, anticipate deskilling effects** due to increased AI integration and maintain **high standards of patient care**.

6. Harmonise Quality Management Systems across Regulations

Streamline Quality Management System (QMS) requirements between the AI Act and Medical Device Regulation with a **unified documentation process**. This will reduce administrative burdens, streamline regulatory compliance, and prevent confusion for healthcare providers using AI.

7. Clarify Deployers' Obligations in Radiology

Provide **clearer guidance** on deployers' obligations, focusing on **safe usage**, **informed patient consent**, and effective **risk communication**. ESR offers its expertise to develop deployment recommendations, focusing on **consistent standards** for quality assurance measures and surveillance across Europe.

8. Caution in the Use of AI Regulatory Sandboxes in Healthcare

Ensure **strict safeguards** and **comprehensive evaluation** for radiology AI tested in regulatory sandboxes. ESR calls for **rigorous large-scale**, **multicentre clinical studies** and **expert oversight**, to ensure AI tools undergo thorough testing before clinical application and protect **patient safety.**

9. Foster Collaboration for Effective Post-Market Monitoring

Promote **standardised** and **interoperable** infrastructures for **collaborative post-market surveillance** between healthcare providers and AI developers, ensuring comprehensive tracking of AI usage and its impact on patient outcomes.

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