**ESR Statement
in response to European Commission White Paper on Artificial Intelligence –
A European approach to excellence and trust**

The European Society of Radiology (ESR) welcomes the European Commission's White Paper on Artificial Intelligence (AI), its recognition of the role of AI in improving healthcare and its approach valuing excellence and trust. We believe that ethics, the respect of data privacy and clinical safety are fundamental considerations in any policy development on new technologies.

Radiology is at the forefront of Artificial Intelligence (AI) in the healthcare sector. Its uses enhance the quality of diagnosis by building on knowledge acquired from patients, and new technologies are revamping the specialty. AI solutions in radiology are beneficial in detecting, characterising and monitoring diseases as well as in high-quality patient care by prioritising imaging exams or generating reports, providing additional time for a patient-doctor relationship.

Therefore, the ESR urges European institutions to consider the following recommendations for the healthcare sector to efficiently embrace AI and to unleash its full potential.

Accessibility of data

Unavailable access to large amounts of varied datasets from across Member States hamper healthcare actors' optimisation of their services and researchers' potential to achieve breakthroughs.

The European Society of Radiology supports the implementation of an EU Health Data Space which would upscale EU-wide cooperation. A strong, efficient and interoperable European framework for the collection of data across borders would foster research development, early detection and early diagnoses of diseases. These outcomes can only be achieved by establishing a robust governance model that sets out how to use health data, while respecting the individual's privacy and transparency rights. For full efficiency and universal use, the ESR believes in drafting EU guidelines for health data to be in the same machine-readable format irrespective of its origin.

Transparency

The collection of personal health data must fully respect the General Data Protection Regulation (GDPR) which states that "the controller shall be able to demonstrate that the data subject has consented to processing of his or her personal data" (Art. 7).

The European Society of Radiology believes that patients should maintain control over their personal information. Besides, the ESR trusts that an individual informed on the responsible management of his or her data and its potential for patient care improvement, will be inclined to consent to the processing of it. The European Commission should support initiatives, such as recommendations and codes of conduct, that are aimed at guiding healthcare professionals and academia in safely collecting, processing, using and re-using data in clinical practice and research.

Considering this, the ESR believes that data collectors should provide clear, openly accessible information about their operations with the data collected.

Data privacy

The collection of health data for public benefit must fully respect individuals' privacies who should trust that their information is processed in full confidentiality. The method for protecting the privacy of patients in accordance with GDPR and other regulations is data anonymisation or pseudonymisation before use.

The European Society of Radiology believes that the effective application of anonymisation would foster cross-border and cross-sector exchanges as well as effective research. Indeed, anonymised data under the regulation on the free flow of non-personal data across Member States, enables for data sharing that is exempt from full documentation or owner approval.

Accountability

In its full support for data privacy and the safety of patients, the European Society of Radiology believes in a EU-level mechanism and an update of the Product Liability Directive for patients and healthcare workers to be protected and covered from any harm caused by breach of law or the use of AI-operated medical devices. EU sectoral legislation (cfr. Medical Device Regulation in healthcare) should be adequately implemented and regularly assessed, considering latest technological developments. Besides, a risk-based approach should be pursued in any cross-sectoral legislative and policy framework to simultaneously strengthen consumer protection, uphold legal certainty and create a level playing field that allows innovation to excel in Europe.

Training and skills

The ESR believes in adequate training for healthcare professionals and citizens to unleash the full potential of AI in health. The EU's role is to support and supplement the action of Member States in their responsibility for education and training systems. Therefore, The European Commission should further its measures laid out in its 2018 Digital Education Action Plan and push for jointly agreed EU quality indicators for continued medical education and changes to university syllabi to include Artificial Intelligence.

Besides, the European Society of Radiology welcomes the European Commission's efforts to close the digital skills gap with EU funding. Adequate investments through programmes including the Digital Europe Programme, Horizon Europe and ESF+ will help forge "AI and digital-educated" organisations and citizens, a prerequisite to unleash the full potential of Artificial Intelligence society-wide and across sectors.

Telemedicine

The recent COVID19 pandemic has unfolded new ways of working and delivering services across all sectors. It has given the opportunity to the radiology field to embrace homeworking and teleradiology to minimise risks of infection for imaging professionals. Further, teleradiology bridges the inequality gaps in healthcare by providing services to populations living in isolation or in medical deserts.

This has advantages but also potential threats to the quality of care provided to patients and to the radiologists' interactions with their clinical colleagues.

The European Society of Radiology supports the implementation of a framework for telemedicine at EU level to ensure high standards of reporting, respect of the EU Health and Safety legislation, clear liability

rules including an update of the product liability directive, verified patient consent and confidentiality, while fully recognising teleradiology as a medical act. Uniform standards for telemedicine would benefit clinicians, patients and healthcare systems in their search for better access, quality and efficiency of healthcare. Currently discussed legislative proposals, such as the digital services act and the update of the product liability directive, offer a window of opportunity to simplify and regulate the safe implementation of telemedicine in Member States.

Harmonisation at EU level

A fragmented approach with various national schemes will hamper the full potential of Artificial Intelligence to improve our lives.

The healthcare sector's research excellence and efficiency in the uptake of AI relies upon EU-wide cooperation, a framework for best practices exchanges between national initiatives and infrastructures as well as an efficient EU health data space. Any initiative, from legislation for high-risk areas to non-binding recommendations for the self-labelling of AI applications, should be furthered with the goal to build confidence among users and support the uptake of trustworthy AI across the EU.

Key messages:

- EU institutions should facilitate the availability and access to large amounts of varied real-world data across borders to unleash the full potential of AI in the European Union
- Disclosure of patient data use should be fully transparent and respect the GDPR requirements
- Respect of privacy and clear liability rules are fundamental in any policy development on new technologies
- Healthcare professionals and citizens should benefit from adequate training across the EU to make AI accessible and beneficial to all
- Telemedicine regulation should be further set in motion to adapt to new realities in Europe and bridge inequality gaps of access to high-quality healthcare
- To unleash the full potential of AI in Europe and make it the hotspot for excellence, harmonisation, interoperability and cooperation at EU level are paramount

The ESR published a white paper that highlights the uses of Artificial Intelligence in radiology, the immediate ethical and professional impact on the specialty and the possible evolution. For more information, please click [here](.).

The European Society of Radiology is an apolitical, non-profit organisation, dedicated to promoting and coordinating the scientific, philanthropic, intellectual and professional activities of Radiology in all European countries. The Society's mission at all times is to serve the health care needs of the general public through the support of science, teaching and research and the quality of service in the field of Radiology.