ESR Statement
European Commission proposal for a European Artificial Intelligence Act

The European Society of Radiology (ESR) welcomes the European Commission's initiative to create the first AI regulation worldwide. However, it recognises the importance of taking into account the specificities of the healthcare field, which require a specific regulatory approach for AI, complementing the currently proposed horizontal, cross-sector regulation. Also, a detailed definition of AI in healthcare is needed in order to be able to tackle regulatory aspects in an effective manner.

- Care must be taken not to prevent or slow down innovation due to overregulation and thus prevent Europe's patients from access to cutting edge healthcare solutions and causing Europe to lose its status as a leader in technological innovation in healthcare.

- Alignment with the requirements laid down in the Medical Device Regulation is needed in order to ensure legal certainty.

- Access to training data is considered to be important from a clinical perspective but requires significant technical infrastructure and repositories. Such data repositories could be coordinated by a centralised body or through cooperation from European medical scientific societies.

- The current provision to use only "error-free and complete" data for training, validation and testing is neither practical nor desirable if testing takes place under real-world conditions. Data sets need to be sufficiently accurate and complete to meet the intended purpose, however the claim for freedom from error is considered inappropriate and would potentially prevent the use of real-world data in healthcare.

- Clinical users of AI need a sound and efficient feedback mechanism with providers of AI solutions for healthcare, such as a direct messaging feature within AI applications to providers, available for radiologists during reporting.

- Human oversight is considered crucial for AI applications in healthcare and the user's autonomy should not be restricted.

- Training of health professionals needs to be adapted to include the use of patient-centred AI in healthcare and to ensure a well-trained workforce.

- The use of AI in healthcare must respect the principles of the GDPR. Additional European guidance and standards would be helpful, including on anonymisation techniques of health data, quality and safety standards etc.

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. Founded in 2005, the ESR is the largest radiological society in the world, with over 122,000 members from 181 countries.