

# Topic 4: Regulatory, Ethical, and AI Considerations for Medical Physicists

This document provides a framework and guidance for the Expert Working Group on Regulatory, Ethical, and AI Considerations, with a specific focus on the roles and responsibilities of medical physicists in navigating the evolving landscape of regulatory frameworks, ethical challenges, and artificial intelligence (AI) in clinical practice. The goal is to identify research needs, gaps in professional education, university foundation knowledge, and CPD (Continuing Professional Development) requirements, ensuring that medical physicists are well-prepared to contribute to the responsible use of AI and adhere to regulatory and ethical standards in medical physics.



## :: 4.1: Regulatory Frameworks ::

### POTENTIAL KEY AREAS TO EXPLORE

- **TGA and International Frameworks (e.g., FDA, EMA):**
  - What are the key regulatory frameworks for medical devices and software in Australia (TGA) and internationally (FDA, EMA)? How do medical physicists navigate these regulations in clinical practice?
  - What are the specific regulatory requirements for AI-powered medical devices and software used in healthcare, and how do these differ across various jurisdictions?
- **Classification of Medical Software/Devices:**
  - How are medical software and devices classified in regulatory frameworks? What criteria determine whether a software or device is considered a medical device, and what implications does this have for medical physicists in their clinical and research work?
- **Clinical Trials and Investigational Use Protocols:**
  - What role do medical physicists play in the design, implementation, and monitoring of clinical trials involving medical devices or AI technologies?
  - How can medical physicists contribute to the development of investigational use protocols, ensuring that they meet regulatory requirements and safety standards?

### POTENTIAL EVALUATION QUESTIONS AND APPROACHES

- **Research Needs:** What research is needed to address gaps in regulatory compliance for AI medical devices? How can medical physicists help bridge these gaps?
- **Future Education Courses:** Should medical physics education programs offer specialised courses on regulatory frameworks for medical devices and software, particularly AI technologies in clinical settings?
- **University Foundation Knowledge:** What foundational knowledge in regulatory affairs, medical device classification, and clinical trial protocols should be embedded in medical physics curricula?
- **CPD Requirements:** What CPD modules should be designed to help practicing medical physicists stay up-to-date on regulatory standards and compliance protocols for medical devices and AI technologies?

## :: 4.2: Ethics in Emerging Technology ::

### POTENTIAL KEY AREAS TO EXPLORE

- **Informed Consent with AI-Assisted Decisions:**
  - How should informed consent be obtained for treatments involving AI-assisted decision-making? What are the ethical considerations for patients when AI tools influence clinical decisions?
  - What is the role of medical physicists in explaining the use of AI systems to patients and ensuring they understand the implications of AI-assisted decisions?
- **Data Privacy and Secondary Data Use:**
  - How do medical physicists ensure that patient data privacy is maintained when working with AI models and healthcare data? What ethical frameworks govern secondary data use in AI research and clinical practice?
  - What are the implications of data sharing and anonymised datasets in the context of AI development for medical devices?
- **Algorithmic Bias and Patient Safety:**
  - What are the potential risks of algorithmic bias in AI systems, particularly in clinical decision-making? How can medical physicists help identify and mitigate bias in AI models to ensure equitable and safe patient care?
  - How should medical physicists contribute to discussions on patient safety in the context of AI technologies, ensuring that AI models are tested and validated for fairness and reliability?

### POTENTIAL EVALUATION QUESTIONS AND APPROACHES

- **Research Needs:** What research is required to improve the ethical frameworks around AI in healthcare? How can medical physicists contribute to addressing algorithmic bias, data privacy, and informed consent issues?
- **Future Education Courses:** Should medical physics education programs include more content on ethics, particularly informed consent, data privacy, and the ethical challenges posed by AI-assisted decisions?
- **University Foundation Knowledge:** What core knowledge in bioethics, data privacy laws, and AI ethics should be included in medical physics curricula to equip students with the tools to navigate emerging ethical issues?
- **CPD Requirements:** What CPD programs are needed to ensure practicing medical physicists are well-versed in AI ethics, patient safety, and the regulatory landscape surrounding data use and informed consent?

## :: 4.3: AI in Medical Physics ::

### POTENTIAL KEY AREAS TO EXPLORE

- **Model Training and Validation:**
  - How are AI models trained and validated in medical physics applications (e.g., imaging, radiation therapy)? What role do medical physicists play in ensuring that these models are accurate and clinically reliable?
  - What is the process for validating AI models used in medical imaging, treatment planning, or other clinical tools, and how can medical physicists contribute to this process?
- **Black-Box Models vs Explainable AI:**
  - What are the challenges associated with black-box models in medical physics, and how can these challenges be addressed? Should medical physicists be involved in the development of explainable AI to ensure transparency in clinical decision-making?
  - How do black-box models affect the role of medical physicists in quality assurance (QA) and clinical governance? What responsibility do medical physicists have in verifying the outputs of AI systems?
- **Deployment in Clinical Workflow:**
  - How can AI technologies be successfully integrated into existing clinical workflows in radiation oncology, imaging, or other medical physics sub-specialties? What role do medical physicists have in ensuring that AI systems enhance clinical workflows without disrupting safety or efficacy?
  - What steps are needed to deploy AI systems safely in clinical environments? How can medical physicists facilitate the smooth integration of these technologies into routine clinical practices?
- **Role of the Physicist in AI QA and Governance:**
  - What is the role of medical physicists in the quality assurance (QA) and governance of AI technologies used in healthcare? How can medical physicists help design and implement QA protocols to ensure AI systems meet clinical standards?
  - What ethical and regulatory considerations should medical physicists be aware of when overseeing the governance and implementation of AI-driven tools in healthcare?

### POTENTIAL EVALUATION QUESTIONS AND APPROACHES

- **Research Needs:** What further research is required to improve AI model validation, black-box model transparency, and the deployment of AI in clinical settings? How can medical physicists help bridge gaps in AI implementation?
- **Future Education Courses:** Should medical physics education programs place greater emphasis on AI technologies, model training, and explainable AI? What specific skills should be taught to prepare students to integrate AI into medical physics practice?
- **University Foundation Knowledge:** What foundational knowledge in AI model validation, clinical deployment, and quality assurance should be embedded in medical physics curricula to ensure preparedness for the integration of AI into healthcare?
- **CPD Requirements:** What CPD modules are needed to ensure that practicing medical physicists are capable of managing and overseeing AI quality assurance, clinical governance, and the integration of AI tools in their respective fields?