***Appendix Table 1** – A glossary of main terms used in the FUTURE-AI guideline (ranked alphabetically).*

Term	Definition
AI auditing	A periodic evaluation of an AI tool to assess its performance and working conditions over time, and to identify potential problems.
AI deployment	The process of placing a completed AI tool into a live clinical environment where it can be used for its intended purpose.
AI design	Early stage of an AI's production lifetime, during which specifications and plans are defined for the subsequent development of the AI tool
AI development	The process of training AI models and building AI-human interfaces, based on the specifications and plans from the AI design phase.
AI evaluation	The assessment of an AI tool's added value in its intended clinical setting.
AI model	A program trained using a machine learning algorithm to perform a given task based on specific input data.
AI monitoring	The process of tracking the behaviour of a deployed AI tool over time, to identify potential degradation in performance and implement mitigation measures such as model updating.
AI regulation	A set of requirements and obligations defined by public authorities, that AI developers, deployers and users must adhere to.
AI risk	Any negative effect that may occur when using an AI tool.
AI tool	A software that comprises the AI model plus a user interface that can be used by the end-users to perform a given AI-powered clinical task.
AI training	The process of using machine learning algorithms to build AI models that learn to perform specific tasks based on existing data samples.
AI updating	The process of re-training or fine-tuning the AI model after some time to improve its performance and correct identified issues.
AI validation	The assessment of an AI model's performance.
Attribute	Personal quality, trait or characteristic of an individual or group of individuals, such as sex, gender, age, ethnicity, socioeconomic status or disability. Protected attributes refer to those attributes that, by law, cannot be discriminated against (*i.e.* attributes that are protected by law).
Benchmarking	The practice of comparing the performance of multiple AI tools (or an AI tool against the standard practice) based on a common reference dataset and a set of predefined performance criteria and metrics.
Bias	Systematic, prejudiced errors by an AI tool against certain individuals or subgroups due to inadequate data or assumptions used during the training of the machine learning model.
Clinical safety	The capability of an AI tool to keep individuals and patients safe and not to cause them any harm.
Clinical setting	The environment or location where the AI tool will be used, such as a hospital, a radiology department, a primary care centre, or for home-based care.
Clinical utility	The capability of an AI tool to be useful in its intended clinical settings, such as to improve clinical outcomes, to increase the clinicians' productivity, or to reduce healthcare costs.
Concept drift	Changes in relationship between AI model inputs and outputs.
Data drift	Changes in the distribution of the AI model's input data over time.
Data quality control	The process of assessing the quality of the input data, to identify potential defects that may affect the correct functioning of the AI tool.
Deployable AI	AI developed with a high technology readiness level (TRL) (5-9) intended for deployment in clinical practice.
Ethical AI	AI that adheres to key ethical values and human rights, such as the rights to privacy, equity and autonomy.

Explainability	The ability of an AI tool to provide clinically meaningful information about the logic behind the AI decisions.
Fairness	The ability of an AI tool to treat equally individuals with similar characteristics or subgroups of individuals including under-represented groups.
Human oversight	A procedure or set of procedures put in place to ensure an AI tool is used under the supervision of a human (*e.g.* a clinician), who is able to overrule the AI decisions and take the final clinical decision.
Intended use	Clinical purpose or clinical task that the AI tool aims to realise in its intended clinical setting.
Logging	The process of keeping a log of events that occur while using an AI tool, such as user actions, accessed and used datasets, clinical decisions, and identified issues.
Proof-of-concept AI	AI developed with a low machine learning technology readiness level (ML-TRL) (1-4) to demonstrate the feasibility of a new AI method or new AI concept.
Real world	The clinical environment in which AI tools will be applied in practice, outside the controlled environment of research labs.
Responsible AI	AI that is designed, developed, evaluated, and monitored by employing an appropriate code of conduct and appropriate methods to achieve technical, clinical, ethical, and legal requirements (*e.g.* efficacy, safety, fairness, robustness, transparency).
Robustness	The ability of an AI tool to overcome expected or unexpected variations, such as due to noise or artefacts in the data.
Third-party evaluator	An independent evaluator who did not participate in any way in the design or development of the AI tool to be evaluated.
Traceability	The ability of an AI tool to be monitored over its complete lifecycle.
Trustworthy AI	AI with proven characteristics such as efficacy, safety, fairness, robustness, transparency, which enable relevant stakeholders such as citizens, clinicians, health organisations and authorities to rely on it and adopt it in real-world practice.
Trustworthy AI vs. Responsible AI	For trustworthy AI, the emphasis is on the characteristics of the AI tool and how they are perceived by the stakeholders of interest (*e.g.* patients, clinicians), while for responsible AI, the emphasis is on the developers, evaluators and managers of the AI tool, and the code of conduct and methods they employ to obtain trustworthy AI tools.
Universality	The ability of an AI tool to generalise across clinical settings.
Usability	The degree to which an AI tool is fit to be used by end-users in the intended clinical setting.

***Table 2** – List of stakeholder groups (ranked alphabetically) that can benefit from the FUTURE-AI guideline.*

Stakeholders	FUTURE-AI usage
AI ethicists	o To embed ethics into the development of medical AI tools.
AI evaluators/clinical trialists	o To perform more comprehensive, multi-faceted evaluations of medical AI tools based on the principles of trustworthy AI. o To assess the trustworthiness of AI tools.
Citizens and patients	o To increase literacy about medical AI and trustworthy AI. o To increase engagement in the production and evaluation of medical AI tools.
Conferences/journals	o To promote best practices and new methods for trustworthy AI among researchers reading or publishing scientific papers.

Data managers	○ To support the development and deployment of medical AI tools that are compliant with data protection/governance principles.
Educational institutions	○ To educate students from all disciplines (machine learning, computer science, medicine, ethics, social sciences) on the principles and approaches for trustworthy AI.
Funding agencies	○ To promote new research projects that integrate best practices and new approaches for responsible AI.
Health organisations	○ To guide healthcare organisations in the evaluation, deployment and monitoring of medical AI tools. ○ To verify the trustworthiness of AI tools.
Healthcare professionals	○ To adopt the principles of trustworthy AI and best practices among the healthcare professions. ○ To engage clinicians in the design, development, evaluation and monitoring of medical AI tools.
IT managers	○ To promote IT solutions for the deployment and monitoring of trustworthy and secure AI tools in clinical practice.
Legal experts	○ To ensure compliance with applicable laws and regulations related to medical AI and data protection.
Manufacturers of medical AI devices	○ To adopt best practices for responsible AI within companies. ○ To develop and/or commercialise new AI tools that will be accepted, certified and deployed for clinical use.
Public authorities	○ To adapt existing regulations and policies on medical AI.
Regulatory bodies	○ To enhance the procedures for the evaluation, certification and monitoring of AI tools as medical devices.
Researchers and developers in medical AI	○ To investigate new methods according to the recommendations for trustworthy AI. ○ To develop proof-of-concepts that can more easily transition into deployable AI tools for clinical practice.
Scientific/medical societies	○ To promote the principles of trustworthy AI and best practices among scientific and medical communities.
Social scientists	○ To ensure social and societal dimensions of medical AI are considered.
Standardisation bodies	○ To develop new standards that facilitate the implementation, evaluation and adoption of trustworthy AI tools in healthcare.