# CANCER CARE THROUGH ARTIFICIAL INTELLIGENCE: PRESENT CAPABILITIES, CLINICAL INTEGRATION, AND FUTURE POTENTIAL - A REVIEW

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*The role of Artificial Intelligence and Machine Learning is developing in an exponentially increasing manner in all respects of Human Life, especially in the health field. Ranging from imaging and pathology to genomics, treatment course planning, decision support in a clinical setting, discovery of drugs, and establishment of new parameters for trials, artificial intelligence has come a long way in all realms of oncology.*

*The promises and challenges in reality have been put forth by major prospective implementation and regulation in recent years. The requirements of validation and adoption of AI have been established in this critical analysis, which assimilates evidence not only towards efficient implementation but also towards familiarity with methodology, consideration with ethics, challenges with regulation, and assimilate major contributions in the developmental years. A major role in implementation and regulation can be established with convening a regulation and overlooking body concerning AI validity and during prosecution of ongoing clinical trials*

## Introduction

Oncology is regarded as one among the leading specialties of medicine because this field is always in a state of progression and treats diseases in a way which seems like a puzzle is being unravelled. Moreover, cancer remains one among the leading causes of death and

morbidity in the whole world. Owing to the complexity associated with this field, a massive amount of information referred to above is used in this field, including medical imaging, whole slide imaging in pathology, omics analysis such as genomics, transcriptomics, proteomics, metabolomics, and so on, electronic health records, and real-time information (Lotter W, et al.,2024). AI in Oncology not only symbolizes a series of technical improvements in a linear sequence but is rather a move towards more intelligent oncology in a relative way. Taking into consideration the latest assessment and focusing on regulation, AI in Oncology is moving towards implementation in a clinic setting, but a lot of obstacles have to be overcome in terms of methodology, safety, equity, and governance (Fountzilas, E., et al., 2025).

**Major Areas of Application:**

- **Diagnostic imaging and screening**

The main role of AI here is in identifying and detailing lesions (CT, MRI, mammography), automated volume measurement and RECIST approximation, triage (prioritisation) and assessing risk for screening populations. Deep convolutional neural networks (CNNs) and more transformer-based architectures are predominant these days. Radiomics (handcrafted imaging techniques) continues to serve as a valuable addition in hybrid models.

Evidence/ regulators: Various commercial tools have procured FDA 510(k) clearance or its equivalent for parallel clinical use.

Example: Lunit INSIGHT MMG was granted 510(k) clearance as a radiological CADe/x product for mammography with claims supporting its performance in providing support for detection within mammography workflows. Various studies suggests that cancer detection rates are much higher and sensitivity is enhanced in reader-aided contexts. However, the efficiency of patient level outcomes always is a topic to be scrutinized. ([1] FDA De Novo Decision Summary — Paige Prostate (DEN200080). U.S. Food & Drug Administration. Decision date: Sep 21, 2021. (De Novo file & decision summary PDF) ([1] Lunit INSIGHT MMG — FDA 510(k) Premarket Notification (K211678). FDA access data summary (device description, predicate).

- **Digital Pathology and Computational Pathology**

Whole-slide images (WSI) and deep learning are used to maximum extend in computational pathology to identify tumours, assess disease severity, quantify immune infiltrates and predict molecular biomarkers from histological data. Paige's prostate AI was granted De Novo authorization by FDA in the year of 2021.It marked the introduction of AI into routine pathology workflows. Algorithms could alter slide review time, extrapolate detection sensitivity for small foci and facilitate automated biomarker score. However, ensuring standardisation and generalizability across different scanners, staining protocols.

- **Genomics, Molecular Oncology and Biomarker Prediction**

Numerous studies and reviews reveal that molecular alterations can be predicted from histological images with moderate to high accuracy in the case of certain tumour types; this proves very helpful in case of triaging or flagging specimens for molecular testing when resources are scarce. AI enhances this scenario with variant calling, classification of somatic mutations, integration of multi omics to identify prognostic and predictive signatures, and most importantly inferring molecular phenotypes (microsatellite instability or EGFR mutation) from H&E or imaging through deep learning. (Wang X, et al.2025; Cifci, D., et al. 2021)

- **Clinical decision support, Triage and Prognosis**

AI aids in prognostic modelling (survival prediction), toxicity forecasting, forecast on therapy response and provide recommendations for treatment sequencing. Methods encompass supervised learning for risk models, adjustment of inference for estimating treatment effects and exploratory reinforcement learning for the implementation of sequential treatment policies.

State of evidence: There are wide variety of prognostic models identified in retrospective cohorts and promising trials to assess clinical utility are very uncommon. Explicit human involvement and integration with tumour boards and EHRs, standardized checklists such as CONSORT-AI, SPIRIT-AI should be adopted for safe clinical implementation. (Park, S.H., et al. 2022)

- **Drug discovery and Translational oncology**

AI minimises search space and can detect subtle structure-activity relationships. It also provides generative modelling for lead discovery, virtual screening, ADMET (Absorption, Distribution, Metabolism, Excretion, and Toxicity) prediction, and trial patient stratification.

Evidence and translational activity: To speed up the hustle between coming up something new and enhancing the trial design, pharmaceutical and biotech companies are integrating AI to their mainframe. It also reduces the duration and the cost by:

- In silico screening of billions of molecules
- Predicting drug–target interactions
- Optimizing drug candidates for toxicity, solubility, and off-target effects
- Modelling tumour microenvironment interactions
- Predicting clinical outcomes for early-phase trial design

Regulators are currently in the pursuit of exploring new AI tools to support their trial endpoints and image based pathological readouts in drug development, such as FDA qualification. Recent developments include the qualification of AIM-NASH for liver disease drug development by the FDA. This clearly indicates a vision to embrace AI in trial contexts. (Reuters / FDA qualification of AIM-NASH (2025) — example of AI tool qualified for drug development in adjacent domain.)

**Technical foundations**

- Image models: Includes convolutional neural networks (ResNet, EfficientNet), U-net variants comes into play for segmentation tasks and vision transformers (VIT) for representation of large-scale images.
- Weak supervision & multiple instance learning: It is applicable to WSI (Whole Slide Imaging**)** with labels for each slide but pixel level labels are limited.
- Self-supervised learning: It opens the unlimited potential of large quantities of unlabelled medical images including contrastive learning, masked image modelling.
- Multi modal fusion: Those are architectures that integrate image, pathological reports and tabular EHR and genomics data using layers of concatenation, cross attention or neural graph networks.

Federated learning and privacy preserving machine learning: Includes methods for collaboration on an institutional level. (Rehman, M.H., et al. 2023; Guan, H., et al. 2024

**Validation, Reporting, Regulatory frameworks and Real-world evidence**

- **Study design and reporting**

Some of the best practice frameworks and reporting checklists has been adopted such as TRIPOD+AI (prediction model reporting), CONSORT-AI and SPIRIT-AI (designed for AI trials) and STARD extensions which focuses on diagnostic accuracy. All the above guidelines encourage clear reporting of data sources, development of models, internal and external validation, calibration and performance of subgroups. (BMJ 2024;385: e078378)

- **Regulatory pathways and examples**

Regulatory pathways and methods differ across jurisdictions such as FDA, EU, MDR, UK MHRA. In the case of US; Artificial Intelligence (AI) and Machine Learning (ML) based devices are authorized through 510(k) or De Novo pathways. Review processes may speed up if they are able to cater to unmet needs.

Examples:

- Paige Prostate – Received FDA De Novo authorization (DEN2000080) as an assistive pathology device. Regulatory activity consisted of a breakthrough device designation for Pancancer Detect application. (FDA De Novo Decision Summary — Paige Prostate (DEN200080). U.S. Food & Drug Administration. Decision date: Sep 21, 2021. (De Novo file & decision summary PDF).
- Lunit INSIGHT MMG – Received 510(k) clearance from FDA (K211678) for mammography CADe/x. (Lunit INSIGHT MMG — FDA 510(k) Premarket Notification (K211678). FDA accessdata summary (device description, predicate).

**Evidence for Clinical Effectiveness**

In the light of recent systematic reviews and implementations, AI can enhance detection with the help of primary care detection tools and cancer screening pilots. In addition, it also improves workflow efficiency by use of pre screening and auto contouring processes. Even

now there is clearly a lack of high-quality controlled trials that aid to increases patient centered outcomes (mortality and quality of life). It is observed that prominent agreements is raising on the genres of the context of the intended use and considering of operational integration, training for users, and continued monitoring of performance. (Olawade DB. et al.,2025)

Many regulatory approvals depend solely on analytical and studies on diagnostic performance (sensitivity, specificity etc) instead of just random outcome trials. Major ongoing research in this field includes comprehensive NHS screening and evaluation aims to overcome the setbacks. ( NHS / media reporting on large-scale AI screening trial — coverage (2025). Reports on NHS launching large breast imaging AI trial)

**Technical and Operational Challenges**

- **Data quality, Distributive shift and Standard reporting**

The performance and effectiveness of AI differ on the changes in distribution of training data. Inadequate representation of demographic groups or imaging devices leads to biased and inequities which derails the AI performance. Equity audits, diverse multi-institutional datasets and federated learning along with proper governance and standardization may help to eradicate the issues to a major extend. (Stetson, P.D., Choy, J., Summerville, N. et al. Responsible Artificial Intelligence governance in oncology. npj Digit. Med. **8**, 407 (2025). https://doi.org/10.1038/s41746-025-01794-w)

- **Generalizability and External Validation**

Incomplete journaling of evaluation splits, model training and preprocessing alters reproducibility. TRIPOD+AI and CONSORT-AI come into play to eradicate this issue and their implementation remains incomplete even now. ([1]Huhulea EN, et al. Artificial Intelligence Advancements in Oncology: A Review. (2025). PMID/PMC.)

- **Explainability and Trust**

For the integration of AI outputs into their decision making, doctors and clinicians need to be able to comprehend the rationale or the principle behind these outputs. Since there are no adequate explainability methods it is essential to include human in loop methods for a clear integration of UI (User Interface) / UX (User Experience) gaining the trust of the clinicians.

- **Regulatory, Legal and Lifecycle Issues**

Diverse regulatory frameworks exist such as US FDA, EU regulations and national health systems for their swift handling. Doubts remains on who's to be held accountable for errors in AI assisted diagnoses. To ensure their acceptance, it is very important to have a check on cost effectiveness along with clinical validity. ( IntuitionLabs. AI Medical Devices: 2025 Status, Regulation & Challenges. (Oct/Nov 2025).

- **Privacy, Security and Data Sharing**

Annotation of large volume of datasets proves to be a very significant objective. Perfect balance of privacy with utility should be achieved with strong de identification methods, secure sharing techniques and proper framework for the governance. New methods such federated learning and synthetic data generation are on the course of development but the dangers of re identification and security breaches still exists. (Wang X, et al. Deep Learning for Cancer Detection Based on Genomic and Imaging Data. (2025). PMC)

**Ethical and Equity Considerations**

Even if AI has the potential to lessen delays on diagnosis and workloads but it also enhances the inequalities if its development is flawed. AI governance prioritizes community involvement, audits without any bias, transparency, and proper supervision. Currently, these initiatives are currently advanced by regulatory bodies, civil society and industry. It is also very crucial to facilitate fair access to block the emergence of "AI Deserts" caused by inadequate resources that alters their implementation. (Reuters. US FDA qualifies first AI tool to help speed liver disease drug development. (Dec 2025) — AIM-NASH qualification.)

**Recommendations and Best practices**

- Specify in advance regarding the intended use and population to be targeted. The clinical workflow and necessary hardware such as scanners, imaging protocols should be properly documented. Terminology best suited for the intended regulatory use should be similar to De Novo or 510(k) submissions.

(FDA De Novo Decision Summary — Paige Prostate (DEN200080). U.S. Food & Drug Administration. Decision date: Sep 21, 2021. (De Novo file & decision summary PDF). (Lunit INSIGHT MMG — FDA 510(k) Premarket Notification (K211678). FDA access data summary (device description, predicate).

- Adoption of standardized reporting: With the usage of TRIPOD+AI, CONSORT-AI, SPIRIT-AI and STARD. (Collins, G.S., et al.2024)
- Equity auditing, Marketing monitoring, governance updation and Collaboration focusing on privacy preservation (Guan, H., et al. 2024)

**Conclusion**

AI is constantly revolutionising fields such as diagnostics, prognostication, treatment planning, and drug development. Increase in achievement and device authorisation shows the maturation of the field and ensures a wide coverage, safe and accountable clinical impact. The collective contribution of clinicians, data scientists, regulators, ethicists and patient communities from wide variety of fields has a huge potential which can determine whether can rise up to its maximum capability to improve global cancer outcomes.

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