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TOPICAL REVIEW

Artificial Intelligence in In Vitro Diagnostics (IVD): A Comprehensive Review of the New Frontier

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ABSTRACT The healthcare industry is undergoing a dual transformation driven by digital innovation and sustainability. This paper provides a comprehensive review of the pivotal role of Artificial Intelligence in In Vitro Diagnostics (AI-in-IVD) as the primary enabler of this shift. Through a systematic review of academic literature, market reports, and regulatory documents, we analyze the technological maturity, disruptive potential, and market trajectory of AI across key medical domains. The results indicate that while all areas of medical AI are growing, the IVD sector demonstrates superior potential, with market forecasts projecting a Compound Annual Growth Rate (CAGR) of over *14.8%* to *20.37%* through 2034, driven by its alignment with both digital and sustainable transformations. Our synthesis identifies four key AI-driven frontiers in IVD: *liquid biopsies, digital pathology, multi-omics integration,* and *point-of-care testing*. We demonstrate how these innovations uniquely align with the dual transformation framework by advancing P4 *(Predictive, Preventive, Personalized, Participatory)* medicine while simultaneously promoting healthcare sustainability through resource optimization and decarbonization. The review concludes that the AI-in-IVD sector represents the most strategic frontier for innovation and investment, offering a roadmap for building resilient and equitable healthcare systems, with specific implications discussed for emerging economies with rapidly growing AI ecosystems, such as Vietnam.

INDEX TERMS Artificial intelligence (AI), in vitro diagnostics (IVD), dual transformation, sustainable healthcare, medical technology startups, precision medicine, digital pathology.

I. INTRODUCTION

The global healthcare industry stands at a critical inflection point, contending with a confluence of systemic pressures that demand a fundamental reinvention of its operational status quo. Escalating healthcare expenditures, projected to reach *$491 billion* (2022) globally [1], the demographic reality of an aging population, with *one in six people* worldwide expected to be over age 65 by 2050 [2], and the lingering operational strains exposed by the COVID-19 pandemic [3] have collectively catalyzed an urgent need for transformation. In response, the industry is navigating a *"dual transformation"*: a simultaneous, intertwined revolution in digital capabilities and a strategic pivot towards sustainable practices [4]. This is no longer a theoretical concept but an active force creating unprecedented opportunities for agile startups and forward-thinking businesses.

Artificial Intelligence (AI) has emerged as the principal enabler of this dual change. The first wave of medical AI convincingly demonstrated its value, primarily in diagnostic imaging. By applying deep learning algorithms to medical scans, AI has augmented the capabilities of radiologists, leading to faster and more accurate diagnoses [5]. This has become a mature and validated market, with valuations projected to exceed USD *19.9 billion* by 2032 [6]. However, while impactful, many innovations in this space are becoming incremental improvements to existing workflows [7]. The next, more disruptive wave of AI is poised to redefine the very core of medical decision-making by transforming *In Vitro Diagnostics* (IVD). This strategic pivot is paramount, considering that an estimated *60−70%* of all critical clinical decisions, from diagnosis to treatment, are influenced by information derived from laboratory tests [8], [9]. While

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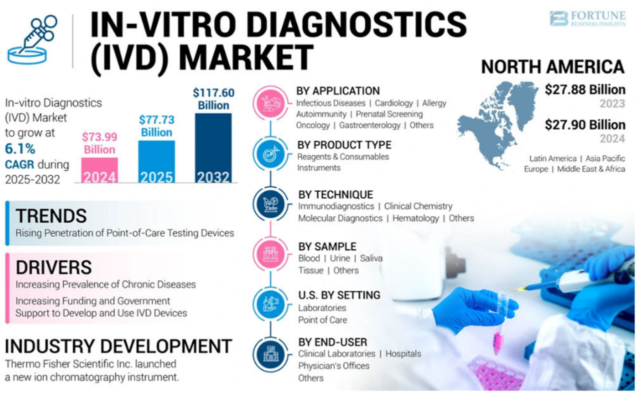

FIGURE 1. In-Vitro diagnostics (IVD) industry landscape overview *source: https://www.fortunebusinessinsights.com/industry-reports/in-vitro-diagnostics-ivd-market-101443.*

images provide crucial anatomical and structural information, IVD data from *blood, urine*, and *tissue samples* offer a dynamic molecular snapshot of a patient's underlying physiology and pathology [10].

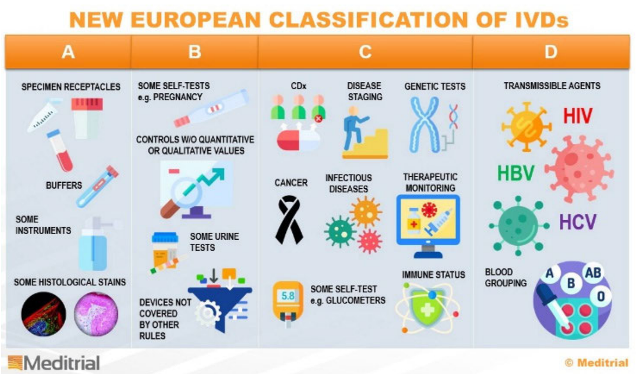

FIGURE 2. Types of In-Vitro diagnostics (IVD) *source: https://www.meditrial.net/2022/06/the-new-good-clinical-practices-for-in-vitro-diagnostic-devices/.*

This strategic shift towards AI in IVD is not merely a technological upgrade; it represents a new business paradigm that perfectly aligns with the twin pillars of the dual transformation (Figure 3).

FIGURE 3. The dual transformation framework.

First, it is the primary engine of Digital Transformation, creating a healthcare system that is more precise, predictive, and personalized [11]. The sheer volume and complexity of IVD data—spanning *genomics*, *proteomics*, *transcriptomics*, and *metabolomics*—exceed the limits of human analysis [12]. AI is uniquely capable of integrating these *multi-omics* datasets to identify subtle patterns and novel biomarkers, fulfilling the promise of precision medicine [13]. This enables the development of revolutionary technologies like liquid biopsies, which can detect cancer at its earliest stages from a simple blood draw [14], and companion diagnostics that accurately predict a patient's response to a specific therapy [15]. The market reflects this potential, with the AI in IVD sector forecast to grow at a compound annual growth rate (CAGR) of over *14.8% (2025-2034)* [16].

Second, AI in IVD is a powerful catalyst for Sustainable Transformation. The healthcare sector has a significant environmental footprint, accounting for an estimated 4.4% of global net carbon emissions—more than the aviation or shipping industries [17], [18]. A substantial portion of this impact stems from inefficiency and waste, estimated to be as high as *25%* of total healthcare spending in the U.S. alone in 2019 [19]. AI-driven diagnostics directly address this by: (a) enabling preventative care, which is inherently less resource-intensive than treating advanced disease [20]; (b) reducing the immense waste from ineffective *"trial-and-error"* treatments by ensuring the right drug is given to the right patient [21]; and (c) lowering the industry's carbon footprint by powering decentralized point-of-care tests (POCT) that reduce patient and sample transportation [22], [23].

Despite the rapid proliferation of AI in healthcare, current literature remains heavily skewed towards diagnostic imaging, leaving the transformative potential of AI in In Vitro Diagnostics (IVD) under-explored. This paper addresses this critical gap by conducting a domain-specific analysis of the IVD sector. The key contributions of this study are threefold:

- *Identification of Technological Frontiers:* We systematically identify and analyze *four convergent drivers*—liquid biopsies, digital pathology, multi-omics integration, and point-of-care testing—that are redefining the diagnostic landscape.
- *Framework Application:* We apply the *"Dual Transformation"* framework to demonstrate how these technologies uniquely advance both precision medicine (Digital) and decarbonization (Sustainability) simultaneously.
- *Strategic Roadmap for Emerging Economies:* We provide specific strategic implications for developing nations, using Vietnam as a case study for how to leapfrog legacy healthcare infrastructure using AI-first diagnostics.

For entrepreneurs and business leaders—particularly those engaged in *"Start-up and business"* — this convergence unlocks a fertile ground for high-impact ventures. This paper will analyze the current landscape of AI in medical devices to build a conclusive case for prioritizing the IVD sector. It will outline the key technological trends, emergent business opportunities, and the profound strategic implications of this critical shift.

II. LITERATURE REVIEW

A review of the current landscape of Artificial Intelligence (AI) in medical devices reveals four primary domains of application: *Diagnostic Imaging, In Vitro Diagnostic, Clinical Monitoring, Treatment*. These domains are differentiated by their technological maturity, market trajectory, and ultimate impact on the healthcare value chain. An analysis of the literature demonstrates a clear evolutionary path, moving from the mature application of AI in imaging towards the nascent, but profoundly disruptive, frontier of In Vitro Diagnostics (IVD).

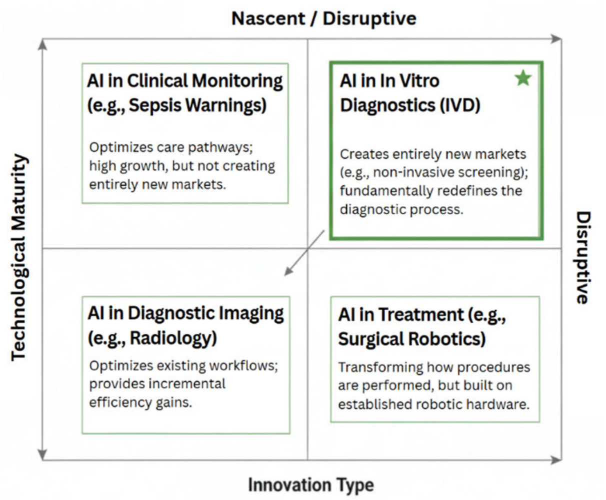

FIGURE 4. Strategic positioning of AI in healthcare: The shift to disruptive IVD. A comparative analysis mapping key medical AI domains across technological maturity and innovation type. AI in diagnostic imaging sits in the mature/sustaining quadrant, optimizing current practice. In contrast, AI in in vitro diagnostics (IVD)occupies the nascent/disruptive quadrant, demonstrating the highest potential for creating new clinical paradigms and fundamentally redefining the healthcare value chain, aligning perfectly with the dual transformation mandate.

A. AI IN DIAGNOSTIC IMAGING: THE MATURE PIONEER

Diagnostic imaging is unequivocally the most mature and widely adopted application of AI in clinical medicine [5], [24]. Leveraging decades of research in computer vision, deep learning algorithms—particularly convolutional neural networks (CNNs)—have proven exceptionally effective at analyzing medical images with a speed and accuracy that can meet or exceed human performance [25]. The applications span numerous modalities and clinical needs, including the detection of *lung nodules* on chest CT scans [26], the identification of *diabetic retinopathy* from fundus images [27], the classification of *skin lesions* [28], the detection of *intracranial hemorrhage* on head CTs [29], and the enhancement of *breast cancer* screening through improved mammogram interpretation [30].

The clinical and workflow benefits have created a robust commercial ecosystem. The global AI in medical imaging market is substantial, valued at several billion dollars and projected to grow at a strong Compound Annual Growth Rate (CAGR) of over *25%* through the end of the decade [31], [32]. The U.S. Food and Drug Administration (FDA) has cleared or approved hundreds of AI/ML-enabled medical devices, the vast majority of which are in the field of radiology [33]. However, this maturity also signals market saturation. While still growing, the field is becoming crowded with vendors offering similar solutions (e.g., for lung nodule detection or stroke triage), leading to innovation that is often incremental rather than paradigm-shifting [7], [34]. The primary function of these tools remains the augmentation of existing clinical workflows, making them more efficient but not fundamentally altering the diagnostic process itself.

B. AI IN CLINICAL EXAMINATION AND MONITORING: THE DIGITAL ASSISTANT

This domain encompasses AI tools designed to act as a *"digital assistant"* at the point of care, either by aiding in real-time diagnosis or by continuously monitoring patient data to predict adverse events. AI-powered stethoscopes, for example, can analyze heart and lung sounds to detect abnormalities like *murmurs* or *arrhythmia* [35]. In cardiology, AI algorithms for interpreting electrocardiograms (ECGs) have demonstrated cardiologist-level accuracy in identifying a wide range of conditions [36]. Beyond cardiac monitoring, AI has demonstrated exceptional versatility in broader physiological analysis. Recent studies have successfully applied deep learning to diverse domains, ranging from posture classification [37] and electromyogram-based gesture recognition [38] to advanced neural network optimizations for temporal sensitivity [39], [40], illustrating the ubiquity of data-driven approaches across the healthcare spectrum.

A more critical application lies in predictive monitoring within *acute care* settings. AI systems can analyze streams of data from electronic health records (EHRs) and bedside monitors to provide early warnings for sepsis [41], [42], *acute kidney injury* [43], and general patient deterioration [44]. These tools serve as clinical decision support systems, helping to prioritize clinician attention and enable earlier intervention. The broader *"AI in diagnostics"* market, which includes these tools, was valued at approximately *USD 1.59 billion* in 2024 and is projected to grow at a *CAGR of 22.46%* [45]. While highly promising, these applications, similar to imaging, primarily augment and optimize existing care pathways rather than creating entirely new ones.

C. AI IN TREATMENT VIA DEVICES: THE PRECISION INTERVENTIONALIST

Beyond diagnostics, AI is increasingly integrated directly into therapeutic devices to deliver more precise, personalized, and adaptive treatments. In robotic surgery, AI enhances the surgeon's capabilities through improved 3D visualization, tremor reduction, and automated instrument tracking, with future systems aiming for greater autonomy in routine surgical subtasks [46], [47]. The market for surgical robots is expanding rapidly, driven by these technological advancements [48].

In *chronic disease* management, AI is the core technology behind *"artificial pancreas"* or closed-loop systems for *Type 1 diabetes*. These devices use AI algorithms to continuously monitor glucose levels and automatically adjust insulin delivery, significantly improving glycemic control and reducing the burden of care on patients [49], [50]. Another key area is *adaptive radiotherapy*, where AI is used to adjust a patient's radiation treatment plan in real-time based on daily changes in tumor size and position, thereby maximizing dose to the tumor while sparing healthy tissue [51]. This segment is part of the broader AI in healthcare market, which is experiencing explosive growth and is projected to become a multi-hundred-billion-dollar industry [52].

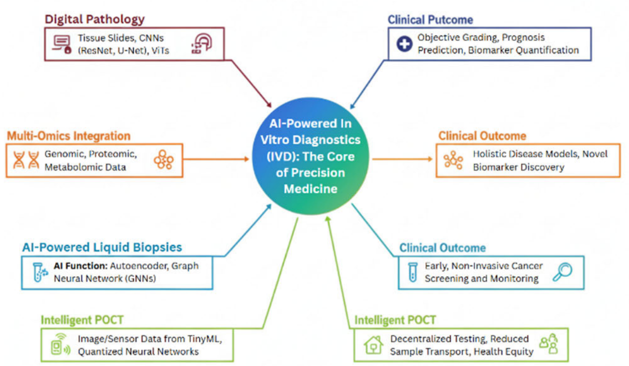

FIGURE 5. The AI in IVD Ecosystem: Technological Drivers and Clinical Outcomes. This diagram illustrates the convergence of high-dimensional biological data sources (outer orange boxes) with advanced AI architectures (green center). The flow demonstrates how inputs such as digitized tissue slides and genomic sequences are processed by specific AI models (e.g., CNNs, GNNs) to drive four distinct clinical frontiers: Liquid Biopsies, Digital Pathology, Multi-omics Integration, and Intelligent POCT. This ecosystem creates a feedback loop that enhances precision medicine while enabling decentralized care. The central circle represents the core value of AI-driven precision medicine. The four outer nodes depict the specific technological inputs (e.g., digitized slides, genomic data) that feed into AI models. These inputs are processed to produce the clinical outcomes shown in the connecting boxes, such as early non-invasive cancer detection (Liquid Biopsy) or decentralized testing (POCT), illustrating how high-dimensional data is converted into actionable clinical insights.

D. AI IN IN VITRO DIAGNOSTICS (IVD): THE DISRUPTIVE FRONTIER

While the aforementioned domains are transformative, the literature suggests that the most fundamentally disruptive frontier for medical AI lies within In Vitro Diagnostics [53]. The data derived from biological samples—encompassing *genomics, transcriptomics*, *proteomics*, and *metabolomics*—are exponentially more complex and higher-dimensional than imaging or physiological data [12], [54]. This *"multi-omics"* data landscape is an ideal substrate for advanced AI models capable of identifying patterns invisible to human analysis [55].

This potential is reflected in aggressive market forecasts, with the AI in IVD market projected to grow at a CAGR of over *14.8%* (2025-2034) [16], *20.37%* (2025-2034) [56]. This growth is not based on improving existing tests alone but on enabling entirely new diagnostic paradigms:

- *Liquid biopsies:* AI is essential for analyzing *circulating tumor DNA* (ctDNA) in blood samples to detect cancer non-invasively at very early stages [14], [57]. Specifically, analyzing low-concentration ctDNA requires sophisticated signal processing and machine learning models like *Support Vector Machines* (SVMs) or *Gradient Boosted Trees* to filter the signal from the noise. Furthermore, AI algorithms are needed to interpret complex methylation patterns [58], a task that often relies on probabilistic graphical models or custom deep learning architectures to identify cancer-specific signatures.
- *Digital pathology:* AI is revolutionizing histopathology by converting glass slides into high-resolution digital images that can be analyzed algorithmically. This is primarily achieved using *Convolutional Neural Networks* (CNNs), such as U-Net for cell segmentation and ResNet for classification tasks, which enable objective and reproducible cancer grading (e.g., Gleason grading for prostate cancer) [59] and biomarker quantification (e.g., PD-L1, HER2) [60]. More advanced *Vision Transformers* (ViTs) are now being used to analyze these whole-slide images (WSIs), capturing broader contextual information to predict *genetic mutations* directly from the tissue's morphology [61]. The FDA has begun to approve AI tools for pathology, signaling a major clinical and regulatory shift [62].
- *Multi-omics integration:* The sheer complexity of integrating disparate datasets from genomics, proteomics, and metabolomics is a primary challenge that AI is uniquely positioned to solve [12]. This integration is being tackled by advanced models such as autoencoders for creating unified low-dimensional representations and Graph Neural Networks (GNNs) to model the complex interactions between genes, proteins, and metabolites, thereby uncovering novel disease pathways and biomarkers [55].
- *AI-driven drug discovery and companion diagnostics (CDx):* AI is accelerating the identification of novel biomarkers that can predict a patient's response to a specific drug [21]. This helps stratify patients for clinical trials, reduces drug development costs, and is the cornerstone of precision medicine [63], [64].
- *Intelligent Point-of-Care Testing (POCT):* AI is being integrated into portable devices, often using smartphone cameras and processors, to provide rapid, low-cost diagnostics at the patient's side. This trend is driven by the field of *Edge AI or TinyML*, which focuses on developing highly efficient, quantized neural network models. These lightweight models can run directly on a device's low-power processor, enabling real-time analysis of images or sensor data without requiring cloud

connectivity. This is particularly impactful for infectious disease diagnosis in resource-limited settings (e.g., automated *malaria* diagnosis from blood smears) and for managing chronic conditions at home [23], [65].

The literature shows significant progress across all domains (Figure 6). However, it also reveals a strategic opportunity. While the imaging and monitoring sectors are characterized by augmentation and optimization of current practices, the application of AI to the foundational data of diagnostics—the biological sample—is creating entirely new clinical capabilities. This represents a shift from a relatively saturated market to a nascent but high-potential area poised for exponential growth and transformative impact.

III. METHODOLOGY

This paper employs a structured narrative synthesis methodology to build its central thesis [66]. This approach is particularly well-suited for addressing broad, strategic questions in a rapidly evolving field like medical technology by systematically analyzing, integrating, and interpreting existing data from a triangulated set of sources. The methodology was executed in three distinct stages, as outlined below and illustrated in *Figure 7*.

A. LITERATURE SEARCH AND SELECTION STRATEGY

A systematic search of the literature was conducted using the *PubMed, IEEE Xplore*, and *Google Scholar* databases for publications between *January 2018* and *October 2025*. Key search terms included combinations of *("Artificial Intelligence"* OR *"Machine Learning")* AND *("In Vitro Diagnostics"* OR *"IVD")* AND *("liquid biopsy"* OR *"digital pathology"* OR *"multi-omics"* OR *"point-of-care testing")*. This academic search was supplemented with a review of grey literature, including recent market analysis reports from firms such as *Grand View Research*, *MarketsandMarkets*, and *Fortune Business Insights*, and publications from regulatory bodies, primarily *the U.S. Food and Drug Administration* (FDA).

B. INCLUSION AND EXCLUSION CRITERIA

The review included peer-reviewed articles, systematic reviews, authoritative industry reports, and government publications relevant to the application of AI in medical devices. Articles not available in English or those focusing purely on theoretical AI without a clear medical application were excluded. The primary focus was on innovations with demonstrated clinical or commercial traction, ensuring the analysis remained grounded in real-world impact and strategic potential.

C. THEMATIC SYNTHESIS AND FRAMEWORK APPLICATION

A narrative synthesis approach [67] was used to analyze the selected literature. The initial synthesis involved a comparative analysis of four key domains of medical AI *(Diagnostic Imaging, Clinical Examination & Monitoring, AI in Treatment,* and *In Vitro Diagnostics)* based on criteria of market growth, technological maturity, and disruptive potential [68].

Following the identification of the IVD sector as the domain with the highest disruptive potential, a deeper thematic synthesis was carried out to identify the primary technological and business trends driving its growth. Finally, these identified trends were systematically analyzed through the specific analytical lens of the *"dual transformation"* framework. This framework was operationalized by defining its two core pillars based on established literature:

1. *Digital transformation:* Assessed by the degree to which an innovation contributes to the principles of P4 Medicine (Predictive, Preventive, Personalized, and Participatory) [69].
2. *Sustainable transformation:* Assessed by the innovation's potential to contribute to healthcare resource optimization, decarbonization [17], and improved accessibility [23].

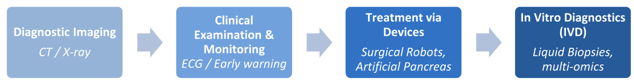

FIGURE 6. Evolution of AI in healthcare.

IV. FINDINGS

The systematic analysis conducted through the three-stage methodology yielded a clear and convergent set of findings. The results unequivocally point to the strategic primacy of the AI in In Vitro Diagnostics (IVD) sector as the central locus of disruptive and sustainable innovation in the medical device landscape. The findings are presented below in three parts, corresponding to the stages of the analysis.

A. FINDING 1: STRATEGIC PRIORITIZATION OF THE IVD SECTOR

The comparative domain analysis revealed that the AI in IVD sector exhibits a superior strategic profile when evaluated against the criteria of market growth, technological maturity, and disruptive potential. As summarized in *Table 1*, while the AI in medical imaging market is currently larger in absolute terms, the AI in IVD market demonstrates a significantly higher projected Compound Annual Growth Rate (CAGR), with multiple forecasts placing it above *14.8%* (2025-2034) [16], *20.37%* (2025-2034) [56].

More critically, the analysis confirmed that IVD innovations are fundamentally ***disruptive***, creating new markets and value networks, in contrast to the largely ***sustaining*** innovations seen in the more mature imaging sector [68]. For example, AI-enabled *liquid biopsies* create a new market for non-invasive cancer screening, a capability that did not previously exist in a scalable form. This contrasts with AI in radiology, which primarily enhances the efficiency and accuracy of an existing diagnostic process. This high growth ceiling, combined with its capacity to redefine clinical pathways, established the IVD sector as the priority domain for further analysis.

TABLE 1. Comparative analysis of four key domains of AI in healthcare.

Domain	Market Size	Projected CAGR	Technological Maturity / Disruptive Potential	Key Examples
Diagnostic Imaging	Established, multi-billion USD	> 25%	**Mature** Saturated market **Sustaining** Optimizes existing workflows	Analysis of CT scans, X-rays, MRI for cancer and stroke detection.
Clinical Examination & Monitoring	Significant (~$1.59B in 2024)	~ 22.5%	**Developing** Highly promising **Sustaining** Augments existing care pathways	ECG analysis, AI-powered stethoscopes, early sepsis warnings.
AI in Treatment	Very Large (Part of broader AI in healthcare market)	Explosive growth	**Developing** Rapidly expanding **Transformative** Creates new treatment modalities	Robotic surgery, artificial pancreas (diabetes), adaptive radiotherapy.
In Vitro Diagnostics (IVD)	Nascent, high potential	**> 26%**	**Nascent** The new frontier **Disruptive** Creates new markets and paradigms	Liquid biopsies, digital pathology, multi-omics integration, POCT.

B. FINDING 2: IDENTIFICATION OF FOUR CONVERGENT TECHNOLOGICAL DRIVERS

The thematic synthesis of the IVD landscape identified four dominant, AI-driven, and mutually reinforcing technological trends as the primary engines of its disruptive potential. These trends represent the core areas of innovation and commercial activity within the sector (Figure 8):

- *AI-Powered liquid biopsies:* The analysis confirmed this as a transformative technology that shifts oncology from invasive tissue biopsies towards minimally invasive blood tests. AI is the critical enabling technology required to detect and interpret the low-frequency signals of *circulating tumor DNA* (ctDNA) and complex *methylation patterns*, thereby enabling early, multi-cancer screening and real-time treatment monitoring [14].
- *AI-Driven digital pathology:* This trend represents the digitization and datafication of histopathology. AI algorithms are converting the traditionally subjective, manual interpretation of tissue slides into an objective, quantitative, and scalable science. This is not only improving diagnostic accuracy and efficiency but also enabling the discovery of novel morphological biomarkers that can predict patient outcomes and genetic mutations directly from an H&E stain [59], [61].
- *Multi-Omics integration:* AI was identified as the only viable tool for integrating the vast and disparate datasets from genomics, proteomics, transcriptomics, and metabolomics. This capability allows for the construction of holistic, high-resolution models of disease biology, leading to the discovery of novel diagnostic biomarkers and therapeutic targets that would be undetectable from any single data stream alone [12].
- *AI-Powered Point-of-Care Testing (POCT):* The results show a strong trend towards the decentralization and democratization of diagnostics, powered by AI. By embedding sophisticated analytical capabilities into smaller, portable devices—often connected to a smartphone—AI is making high-quality diagnostic testing more accessible, affordable, and immediate, moving it from centralized laboratories to clinics, pharmacies, and even the remote area such as patients' home [23].

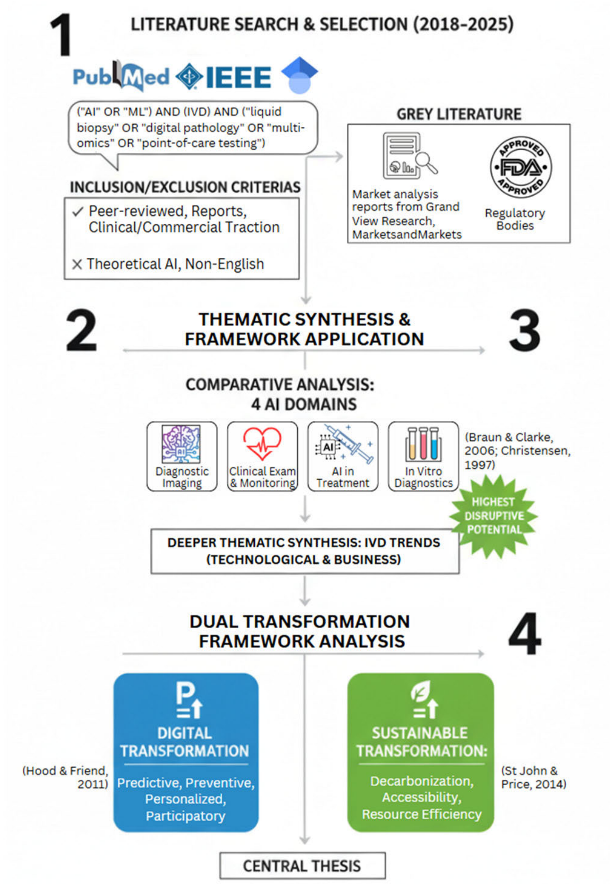

FIGURE 7. Conceptual framework of the review.

C. FINDING 3: CONCLUSIVE ALIGNMENT WITH THE DUAL TRANSFORMATION FRAMEWORK

The application of the dual transformation framework revealed a unique and powerful alignment between the identified IVD trends and the twin imperatives of digital innovation and sustainability. No other domain demonstrated this comprehensive and synergistic contribution.

- *Digital transformation impact:* The four identified trends directly advance a more predictive, personalized, and precise healthcare model, consistent with the principles of P4 Medicine [69]. AI-powered liquid biopsies and multi-omics integration advance predictive and preventive medicine by enabling risk stratification and

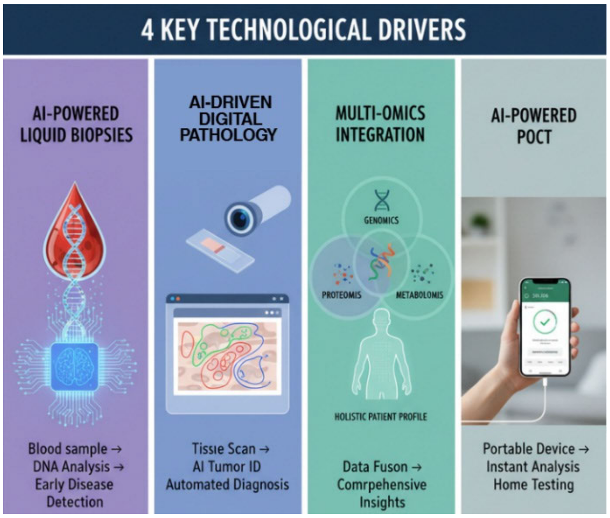

FIGURE 8. **Four key technological drivers *of AI in IVD.* Each column represents a distinct technological trend shaping the future of diagnostics. The visual flow illustrates the transformation of raw biological samples (bottom)—ranging from blood and tissue to biosignals—through AI-driven analysis (middle), resulting in specific diagnostic capabilities (top). This highlights the shift from manual interpretation to automated, high-throughput, and data-driven diagnostic pathways.**

TABLE 2. **Four convergent AI-Driven technological drivers in IVD.**

Technological driver	Description	Role of AI / Key Function	Impact & Key Benefits	References
AI-Powered Liquid Biopsies	Shifts oncology from invasive tissue biopsies to minimally invasive blood tests.	The critical technology for detecting and interpreting low-frequency signals of ctDNA and complex methylation patterns.	Enables early, multi-cancer screening and real-time treatment monitoring.	Ignatiadis et al., 2021
AI-Driven Digital Pathology	The digitization and datafication of histopathology, converting subjective manual interpretation into an objective, quantitative science.	Analyzes tissue slide images to improve diagnosis and discover novel biomarkers.	Improves diagnostic accuracy and efficiency; enables the discovery of new morphological biomarkers to predict outcomes and mutations.	Bera et al., 2019; Coudray et al., 2018
Multi-Omics Integration	The combination of vast and disparate datasets from genomics, proteomics, transcriptomics, and metabolomics.	Serves as the only viable tool for integrating complex datasets to build holistic, high-resolution models of disease.	Leads to the discovery of novel diagnostic biomarkers and therapeutic targets that are undetectable from any single data stream.	Subramanian et al., 2020
AI-Powered Point-of-Care Testing (POCT)	The decentralization and democratization of diagnostics through smaller, portable, and connected devices.	Embeds sophisticated analytical capabilities into portable devices, often connected to a smartphone.	Makes high-quality diagnostic testing more accessible, affordable, and immediate, moving it from labs to clinics, pharmacies, and homes.	St John & Price, 2014

pre-symptomatic disease detection. AI in digital pathology and companion diagnostics is the foundational enabler of personalized medicine, ensuring therapies are targeted to a patient's specific molecular profile.

- *Sustainable transformation impact:* The results show that these same trends make a direct and measurable contribution to healthcare sustainability.
  - *Resource optimization:* AI-driven companion diagnostics promote sustainability by reducing the administration of costly and ineffective therapies, a major source of the estimated $200 billion in annual waste from overtreatment in the U.S. [19].
  - *Decarbonization and accessibility:* AI-powered POCT contributes to the decarbonization of healthcare by significantly reducing the carbon footprint associated with patient and sample transportation to centralized labs, a key component of the sector's emissions [17]. This decentralization also enhances health equity by democratizing access to diagnostics in remote and underserved communities.
  - *Workflow efficiency:* AI in pathology and laboratory automation improves the efficiency of diagnostic workflows, reducing the consumption of energy, reagents, and other material resources per test.

TABLE 3. **Dual transformation impact of convergent IVD technologies.**

Technological Driver	Digital Transformation Impact	Sustainable Transformation Impact
AI-Powered Liquid Biopsies & Multi-Omics Integration	Advances **predictive and preventive** medicine by enabling early, pre-symptomatic detection and risk analysis.	Enables **resource optimization** through companion diagnostics, ensuring expensive therapies are given only to patients who will benefit.
AI-Driven Digital Pathology	Drives **personalized medicine** by providing quantitative, objective analysis for targeted therapy selection (companion diagnostics).	Increases **workflow efficiency**, reducing the consumption of energy, reagents, and other material resources in the lab.
AI-Powered Point-of-Care Testing (POCT)	**Democratizes access** to diagnostics, bringing powerful testing to clinics, pharmacies, and homes.	Promotes **decarbonization** by reducing patient/sample transport and enhances **health equity** in underserved areas.

The preceding analysis has identified the key technological drivers within the AI-in-IVD landscape. We now synthesize these findings through the lens of our central thesis. Table 3 explicitly maps these convergent technologies to the dual transformation framework, illustrating how each innovation simultaneously advances the goals of Digital Transformation (advancing P4 medicine) and Sustainable Transformation (improving resource efficiency, accessibility, and decarbonization).

To synthesize the technical and strategic dimensions of these four domains, Table 4 provides a consolidated overview. The table compares each domain across its primary data source, the specific AI models applied, its core technical challenge, and the strategic opportunity it represents, revealing a clear pattern of progression towards predictive and decentralized healthcare.

TABLE 4. Technical synthesis of AI applications in key IVD domains.

IVD Driver	Primary Data Source	Key AI/ML Models Applied	Primary Technical Challenge	Key Strategic Opportunity
Digital Pathology	Whole-Slide Images (WSI) from tissue biopsies	Signal Processing Algorithms Gradient Boosted Trees, SVMs Deep Learning Architectures	Data Standardization (stain variation); Computational cost of WSI analysis	Uncovering novel morphological biomarkers; Predicting genetic mutations from images
Liquid Biopsies	Cell-free DNA (cfDNA), Circulating tumor DNA (ctDNA) from blood	Autoencoders Graph Neural Networks (GNNs)	Signal-to-noise ratio is extremely low; Biological validation is complex	Non-invasive, early-stage cancer detection and real-time monitoring of therapy response
Multi-Omics Integration	Genomic, Proteomic, Metabolomic, Transcriptomic data	Quantized Neural Networks Edge AI / TinyML Models	High-dimensionality ("curse of dimensionality"); Data heterogeneity and missing values	Discovering novel drug targets; Building holistic, personalized disease models
Intelligent POCT	Images, Sensor readouts, Biosignals from portable devices	Signal Processing Algorithms Gradient Boosted Trees, SVMs Deep Learning Architectures	Model accuracy on low-power hardware; Ensuring robustness in uncontrolled environments	Democratizing diagnostics; Enhancing health equity in remote or low-resource settings

V. CHALLENGES, ETHICAL CONSIDERATIONS, AND FUTURE DIRECTIONS

While the convergence of AI and IVD promises to catalyze a paradigm shift in healthcare, the path from innovation to widespread clinical adoption is fraught with significant challenges. Addressing these hurdles is a prerequisite for realizing the full potential of this technological revolution. The future trajectory of the field will be defined not only by technological advances but also by how stakeholders navigate these complex issues.

A. DATA AND ALGORITHMIC HURDLES

The performance of any AI model is fundamentally dependent on the data used for its training and validation. The most significant technical barrier remains the need for large, high-quality, and diverse annotated datasets. Ethically sourced clinical data is the essential fuel for training robust models [70], yet creating such repositories at scale is a major logistical and financial challenge.

Moreover, a significant proportion of current ML studies rely on small datasets of uncertain quality that have not been subjected to independent prospective peer review. As noted by Collins et al. [71], this raises concerns about whether reported performance metrics will hold up in clinical practice. Additionally, it remains questionable how well models trained on predominantly Western populations will generalize to patients in emerging economies like Vietnam due to significant genetic, environmental, and disease-prevalence differences.

TABLE 5. A framework for navigating challenges in the clinical adoption of AI in IVD.

Challenge Category	Specific Challenge	Impact on Adoption	Mitigation Strategy / Future Direction
Data & Algorithmic Hurdles	Data Scarcity & Diversity.	Hinders model accuracy and creates algorithmic bias, limiting generalizability.	Develop **Federated Learning** models that train on local data without sharing it. Create large, multi-institutional, ethically sourced datasets.
	The "Black Box" Problem	Erodes clinical trust and makes it difficult to validate model reasoning in high-stakes decisions.	Prioritize development and implementation of eXplainable AI (XAI) techniques. Focus on models that provide clear, interpretable outputs
Regulatory & Economic Barriers	Complex Regulatory Pathways	Creates a high barrier to entry for startups due to the cost and time required for AIaMD approval.	Proactive engagement with regulatory bodies (e.g., FDA) to clarify standards for adaptive AI. Develop standardized validation protocols.
	Outdated Reimbursement Models	Creates significant commercial barriers by failing to value the *predictive insight* of an AI test over its physical cost.	Advocate for and develop new value-based reimbursement policies that reward improved patient outcomes and system-wide savings.
Clinical & Ethical Considerations	Clinical Workflow Integration.	Disrupts established laboratory and clinical practices, leading to resistance from healthcare professionals.	Design AI tools with a human-centered approach, ensuring they augment, not replace, clinical expertise and fit seamlessly into workflows.
	Data Privacy & Security	Raises ethical concerns about the use of sensitive genomic and health data, potentially eroding public trust.	Implement robust data governance, including encryption and anonymization. Adhere to data protection regulations such as GDPR (Europe), HIPAA (USA), and relevant local equivalents.

Furthermore, many of the most powerful deep learning models operate as *"black boxes"* making it difficult for clinicians to understand the reasoning behind a specific prediction. In high-stakes medical decisions, this lack of interpretability can be a major barrier to trust and adoption. This has given rise to the field of **eXplainable AI (XAI)**, which seeks to develop models that can provide clear, clinically relevant justifications for their outputs. Finally, there is a significant risk of algorithmic bias. A model trained on data from a specific demographic or geographic population may not generalize well to others, potentially perpetuating or even exacerbating existing health disparities. Ensuring model generalizability across different populations, laboratory settings, and equipment is a critical and ongoing area of research.

B. REGULATORY AND REIMBURSEMENT BARRIERS

Navigating the complex and evolving regulatory pathways for AI as a Medical Device (AIaMD) presents a major challenge, particularly for startups [72]. Regulatory bodies like the U.S.

FDA are continuously developing frameworks for software that can learn and change over time, but the process remains lengthy and resource-intensive.

Perhaps more critically, establishing viable commercial models is hampered by outdated reimbursement structures. Traditional reimbursement systems are designed to pay for the cost of a physical test or procedure, not for the predictive insights generated by a complex algorithm [73]. Without clear policies that value and reimburse the diagnostic intelligence provided by AI, even the most transformative technologies may fail to achieve commercial sustainability and widespread clinical adoption.

C. FUTURE DIRECTIONS: FROM PREDICTIVE TO GENERATIVE AI

Looking forward, the trajectory of innovation is set to accelerate beyond the predictive models that dominate today. The next frontier will involve a pan-diagnostic AI integration, fusing multi-omics data from IVD with insights from digital pathology, medical imaging, and real-time data from wearables to create a comprehensive, dynamic "digital twin" of the patient.

Furthermore, the emergence of Generative AI and Large Language Models (LLMs) promises to shift the paradigm from pattern recognition to hypothesis generation. These models will not only analyze existing data but will also be capable of predicting drug resistance, simulating disease progression at a molecular level and even designing novel biomarkers for undiscovered disease subtypes. This evolution from assistive AI to generative and, eventually, autonomous systems will redefine the speed and scale of diagnostics, creating a healthcare system that is truly predictive and personalized.

VI. DISCUSSION

The results of this analysis have profound implications that extend beyond technology trends into the realms of business strategy, national policy, and entrepreneurship. The unique positioning of AI in In Vitro Diagnostics (IVD) at the nexus of the dual transformation creates a fertile global ecosystem for innovation, a dynamic described by management scholars as a *"paradigm shift"* that opens new avenues for value creation [74]. This is particularly relevant for emerging economies like Vietnam, presenting a strategic opportunity for *"Startups and business in the dual transformation trend"* to leapfrog legacy healthcare systems and build a next-generation infrastructure founded on data-driven, sustainable principles [75].

Globally, the findings signal a fundamental and irreversible shift in the medical device business model, moving away from transactional hardware sales toward integrated, data-centric solutions. The true value is migrating from the physical device to the actionable insights generated by AI algorithms [76]. The most innovative companies are no longer simple device manufacturers but have become data-science organizations. Startups like Guardant Health, with its liquid biopsy platforms, and PathAI, a leader in computational pathology, exemplify this new paradigm by creating recurring revenue streams through *"Diagnostics-as-a-Service"* (DaaS) platforms [77]. They achieve this by licensing specialized algorithms and, crucially, forging deep partnerships with pharmaceutical companies to accelerate clinical trials and develop companion diagnostics [15]. This model offers immense value by de-risking the multi-billion-dollar pharmaceutical R&D pipeline and speeding a drug's time-to-market, representing a transition from product vendor to integrated strategic partner [78].

This disruptive landscape creates a distinct advantage for agile startups. While established giants like Roche, Abbott, and Siemens Healthineers possess immense scale and market access, they can also be encumbered by organizational inertia and legacy product portfolios [68]. Startups, unburdened by these constraints, can attract top-tier AI and bioinformatics talent with purpose-driven missions and a singular focus on innovation [79]. Their ability to iterate rapidly on software-based solutions makes them not only fierce competitors but also essential collaboration partners and attractive acquisition targets for large incumbents seeking to infuse their pipelines with cutting-edge technology, a trend widely observed in the HealthTech sector [80].

For Vietnam, a nation with a burgeoning digital economy and a stated ambition to advance its healthcare system, these global trends are not just observational—they are a strategic roadmap. The *"dual transformation"* in healthcare aligns perfectly with national policies such as the *"National Strategy on the Fourth Industrial Revolution to 2030"* and *Decision No. 749/QD-TTg* on the National Digital Transformation Program [81]. The emphasis on AI, data-driven decision-making, and sustainable development provides a strong policy tailwind for entrepreneurs. The government's focus on cultivating a robust digital economy creates a fertile environment where HealthTech startups can address some of the nation's most pressing healthcare challenges, which are well-documented by bodies like the World Health Organization [82].

The four identified technological drivers offer direct solutions to these local challenges. For instance, AI-powered Point-of-Care Testing (POCT) can help decentralize diagnostics, empowering local clinics and district-level hospitals in rural and remote areas to combat health access disparities [83]. This can alleviate the chronic overcrowding in central hospitals in Hanoi and Ho Chi Minh City [83]. Similarly, with a documented shortage of medical specialists, particularly in fields like pathology [85], AI-driven digital pathology platforms allow a small number of experts at a central institution to remotely review and diagnose cases from across the country, effectively amplifying their expertise and improving the quality of cancer diagnosis nationwide.

Vietnam's primary competitive advantage lies in its strong and growing pool of software engineering and data science talent, a strength recognized in global innovation indices [86]. While developing novel diagnostic hardware or complex biochemical reagents may be capital-intensive, developing the

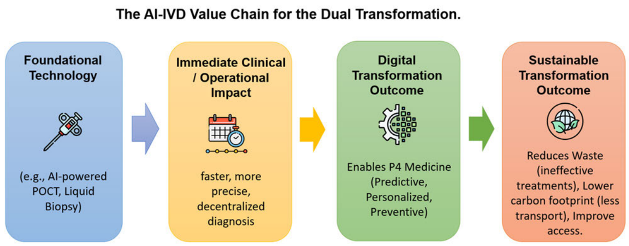

FIGURE 9. **The AI-IVD value chain for the dual transformation. The diagram illustrates the cascading impact of AI adoption. The flow begins on the left with foundational technology(e.g., AI-powered POCT, Liquid Biopsy), which generates an immediate Clinical Operational Impact (faster, decentralized results). This operational shift acts as the catalyst for the broader Digital Transformation Outcome (enabling P4 Medicine) and ultimately delivers the sustainable transformation outcome (reducing waste and improving equity), confirming the strategic alignment of IVD with the dual transformation framework.**

AI algorithms, software platforms, and data analysis pipelines is directly within the nation's core competency. Vietnamese startups can strategically focus on creating the high-value *"brains"* behind the diagnostic revolution, while forming international partnerships for the capital-intensive hardware components, a model successfully employed in other tech sectors.

These findings signal a clear direction for investment, collaboration, and policy. Venture capital and corporate investment should prioritize companies that embrace data-centric, service-based models. For Vietnam, success will hinge on strategic international collaboration. Vietnamese startups should seek partnerships with global pharmaceutical companies for clinical validation, with international MedTech firms for hardware integration, and with leading academic institutions for foundational research. Critically, local healthcare providers must become active partners in providing ethically sourced, well-annotated clinical data, which is the essential fuel for training high-quality AI models [70].

However, significant hurdles remain. Globally, navigating complex and evolving regulatory pathways for AI as a Medical Device (AIaMD) from bodies like the U.S. FDA and the European Medicines Agency is a major challenge [72]. Establishing clear reimbursement models that value the predictive insights of these novel diagnostics, not just the cost of the physical test, is critical for commercial viability [73]. In Vietnam, these challenges are compounded by the need to develop a clear, agile regulatory framework, such as a *"regulatory sandbox"* for HealthTech innovation, and to build the data infrastructure and governance policies necessary for secure data sharing, in compliance with regulations like the Law on Cyber Security and forthcoming data protection decrees [87]. Despite these challenges, the immense clinical and economic value presented by AI in IVD is creating powerful global momentum. For Vietnam, this is a strategic opportunity to harness the dual transformation, leverage its intrinsic strengths, and build a more modern, equitable, and sustainable healthcare system for its citizens.

VII. CONCLUSION

This review has established that the rise of AI in IVD signals a fundamental shift in the medical device business model, moving from hardware sales to integrated, data-centric solutions. For emerging economies like Vietnam, this presents a unique opportunity to leapfrog legacy healthcare infrastructure. The path forward is not to replicate the capital-intensive, centralized systems of the West but to build a decentralized, agile, and digitally native network. By leveraging its primary national asset—a burgeoning pool of high-skilled tech talent—Vietnam can focus on creating the high-value software, algorithms, and data-integration platforms for a new diagnostic era, directly addressing national challenges of health equity and specialist shortages.

In conclusion, for startups, investors, and industry leaders—both globally and in Vietnam—the intersection of AI and IVD represents the single most significant growth and impact opportunity in the medical device landscape. By harnessing AI to make diagnostics more intelligent, predictive, and accessible, we are not just improving patient outcomes. We are building the very foundations of a resilient, equitable, and sustainable future for healthcare.

APPENDIX A
ABBREVIATION LIST

Abbreviation	Full Form
AI	Artificial Intelligence.
LLM	Large Language Models. (LLMs)
IVD	In Vitro Diagnostics.
P4	Predictive, Preventive, Personalized, Participatory.
CAGR	Compound Annual Growth Rate.
CT	Computed Tomography.
CNNs	Convolutional Neural Networks.
ECGs	Electrocardiograms.
EHRs	Electronic Health Records.
FDA	U.S. Food and Drug Administration.
AI/ML	Artificial Intelligence/Machine Learning.
CDx	Companion Diagnostics.
ctDNA	Circulating Tumor DNA.
SVMs	Support Vector Machines.
WSIs	Whole-Slide Images.
ViTs	Vision Transformers.
GNNs	Graph Neural Networks.
POCT	Point-of-Care Testing.
XAI	eXplainable AI.
AIaMD	AI as a Medical Device.
LLMs	Large Language Models.
DaaS	Diagnostics-as-a-Service.
R&D	Research and Development.
WHO	World Health Organization.
WIPO	World Intellectual Property Organization.
WSI	Whole-Slide Images.

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