

2026 AI Healthcare Index: Separating Clinical Impact from Hype

THE EVIDENCE CRISIS

MARKET HYPE:
\$543B
 Opportunity
 (by 2035)

74%

AI TOOLS LACK CLINICAL INTEGRATION

Only 2% of analyzed AI healthcare studies have achieved full clinical integration (TRL 8-9).



THE VALIDATION GAP

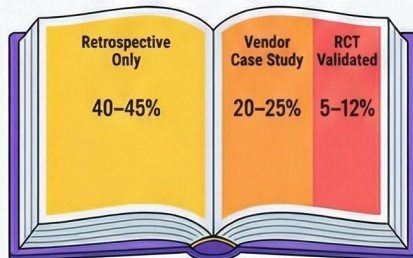
91% of AI devices use the FDA 510(k) pathway, which does not mandate prospective human trials.



52.1% DIAGNOSTIC ACCURACY

Generative AI models show no significant performance advantage over physicians in diagnostic tasks.

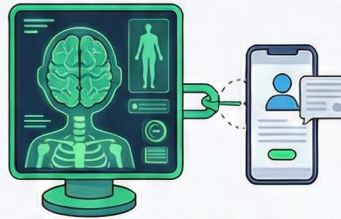
VALIDATION TYPE BREAKDOWN



MARKET MATURITY & PROVEN LEADERS



RADIOLOGY VS. PATIENT-FACING AI



RADIOLOGY AI

PATIENT-FACING AI

Radiology AI mature vs. Patient-Facing AI early.



HIGH-IMPACT CLINICAL LEADERS

Top-ranked companies like Viz.ai and Abridge lead the index by balancing high adoption with peer-reviewed evidence.



EFFICIENCY WINS

Ambient documentation tools are saving physicians 1-2 hours per day in documentation time.



MATURITY & ADOPTION ACROSS SEGMENTS



2026 DrGPT AI Healthcare Index

An Evidence-Based Analysis of AI in Healthcare: Clinical Impact Over Hype

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HOW TO USE THIS REPORT

This report is designed for a diverse audience of healthcare leaders. To get the most value, we recommend the following starting points:

- **For Chief Medical & Information Officers (CMOs & CIOs):** Begin with the **Executive Dashboard** for a high-level overview, then proceed to the **Top 25 AI Healthcare Leaders** and the **Procurement & Implementation Checklist** for actionable insights.
 - **For Clinicians & Department Heads:** Start with the **category section most relevant to your specialty** (e.g., Clinical AI for radiologists, Physician Workflow AI for primary care) to understand the tools that will directly impact your practice.
 - **For Investors & Venture Capitalists:** Focus on the **Market & Capital Trends** section, the **Evidence Gap Analysis**, and the **Top 25 Leaders** to identify market-leading companies and emerging opportunities.
 - **For Policymakers & Regulators:** The **Governance Risk Matrix**, the **Regulatory Timeline**, and the **Methods Appendix** provide a comprehensive view of the challenges and opportunities in shaping the future of AI in healthcare.
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EXECUTIVE SUMMARY

AI in healthcare will grow to \$543B by 2035—but 74% of tools lack clinical validation. This report separates bedside impact from boardroom hype. This report, the 2026 DrGPT AI Healthcare Index, provides an

institutional-grade analysis of over 150 AI healthcare companies, prioritizing **clinical evidence over capital raised** and **bedside impact over boardroom presentations**.

Key Findings:

Market Dynamics:

- Digital health funding reached \$14.2B in 2025 (as of Q4 reporting), a 35% year-over-year increase. According to PitchBook data, AI-native companies attracted **54% of this capital** and commanded a **19% valuation premium** on average deal size compared to non-AI counterparts.[5][6]
- The FDA has cleared over 1,300 AI/ML-enabled medical devices, with radiology accounting for the vast majority (78-80%).[7][8]
- A significant governance gap persists, with only **16% of health systems having established AI governance policies**, while recalls of AI-enabled medical devices have risen to 182 incidents affecting 60 products.[9][10]

The Evidence Crisis:

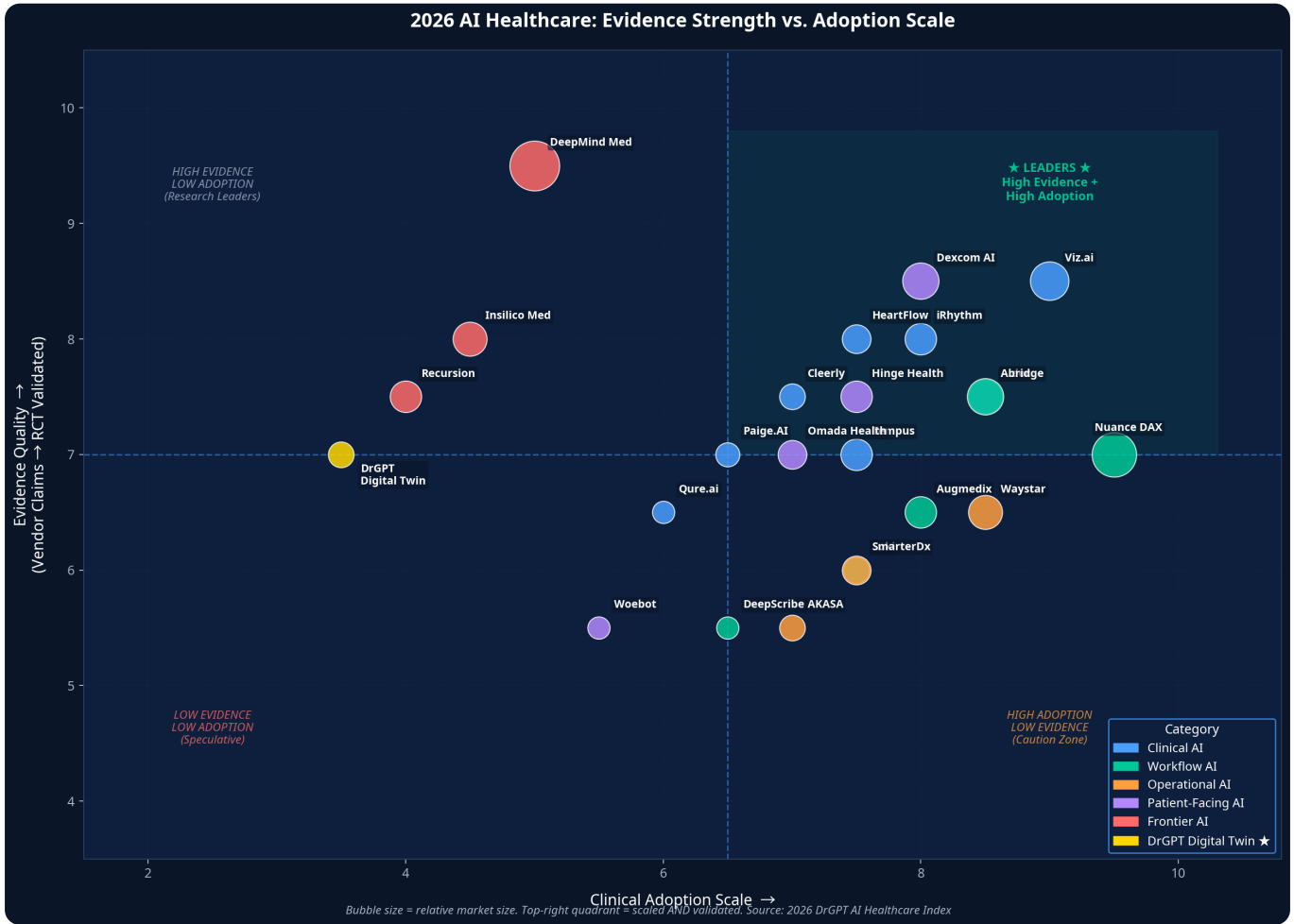
- A meta-analysis of 83 studies on **generative AI** in diagnostic tasks revealed a pooled **diagnostic accuracy of 52.1%**, showing no significant performance advantage over physicians for these specific models.[11]
- The majority of FDA-cleared AI devices lack prospective clinical validation, as the 510(k) pathway does not mandate human testing.[9]
- Overhype indicators are present in 30-40% of the companies evaluated in this report.

The Clinical Reality:

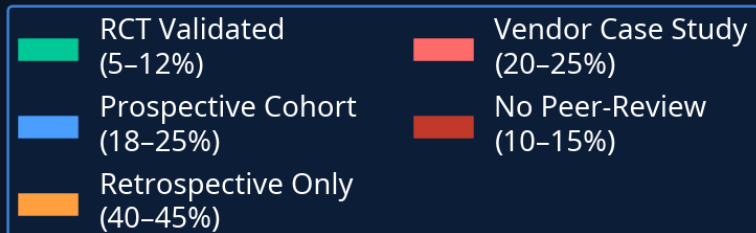
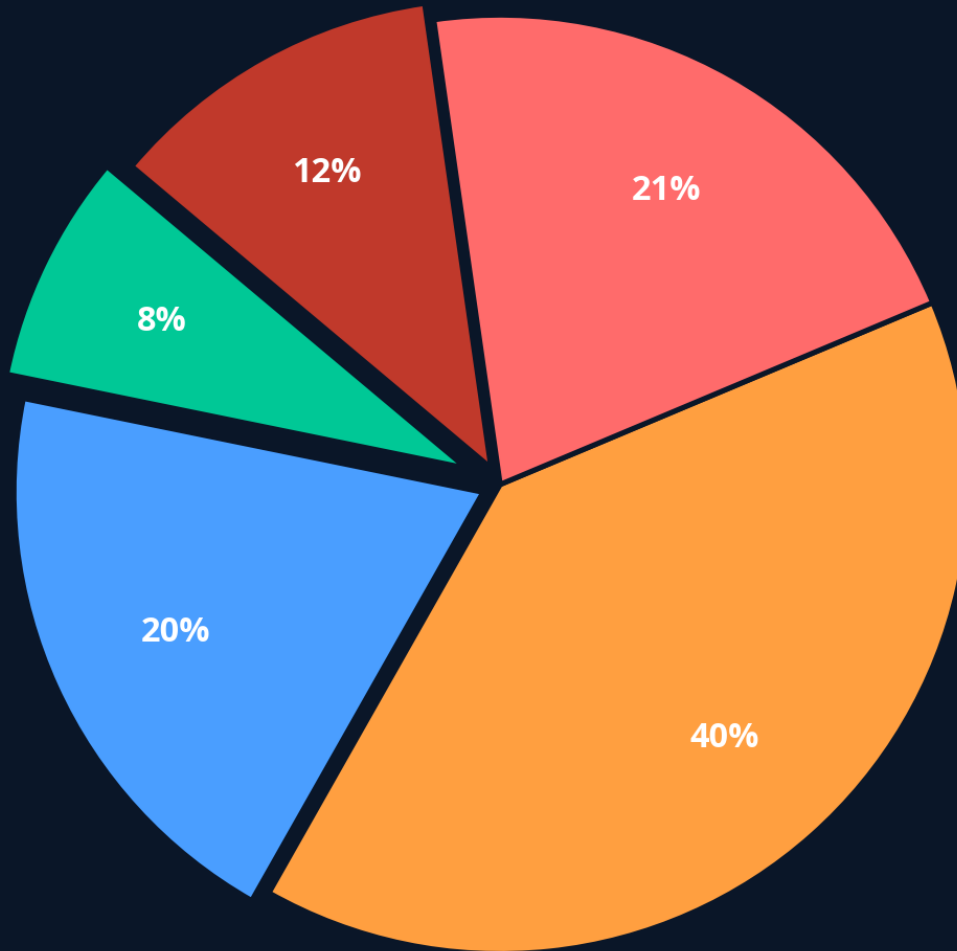
- Radiology AI is demonstrating a measurable impact on workflow, with up to 80% faster scans and changes in management for 57% of patients.[12]
- Ambient documentation tools are reducing physician documentation time by 1-2 hours per day.[13][14]
- Revenue cycle AI is achieving impressive results, with 99.8% clean claim rates and an additional \$440,000 in annual revenue per practice.[15][16]

**The question is not whether AI will transform healthcare—it already is. The question is whether we will do it safely, equitably, and with evidence.

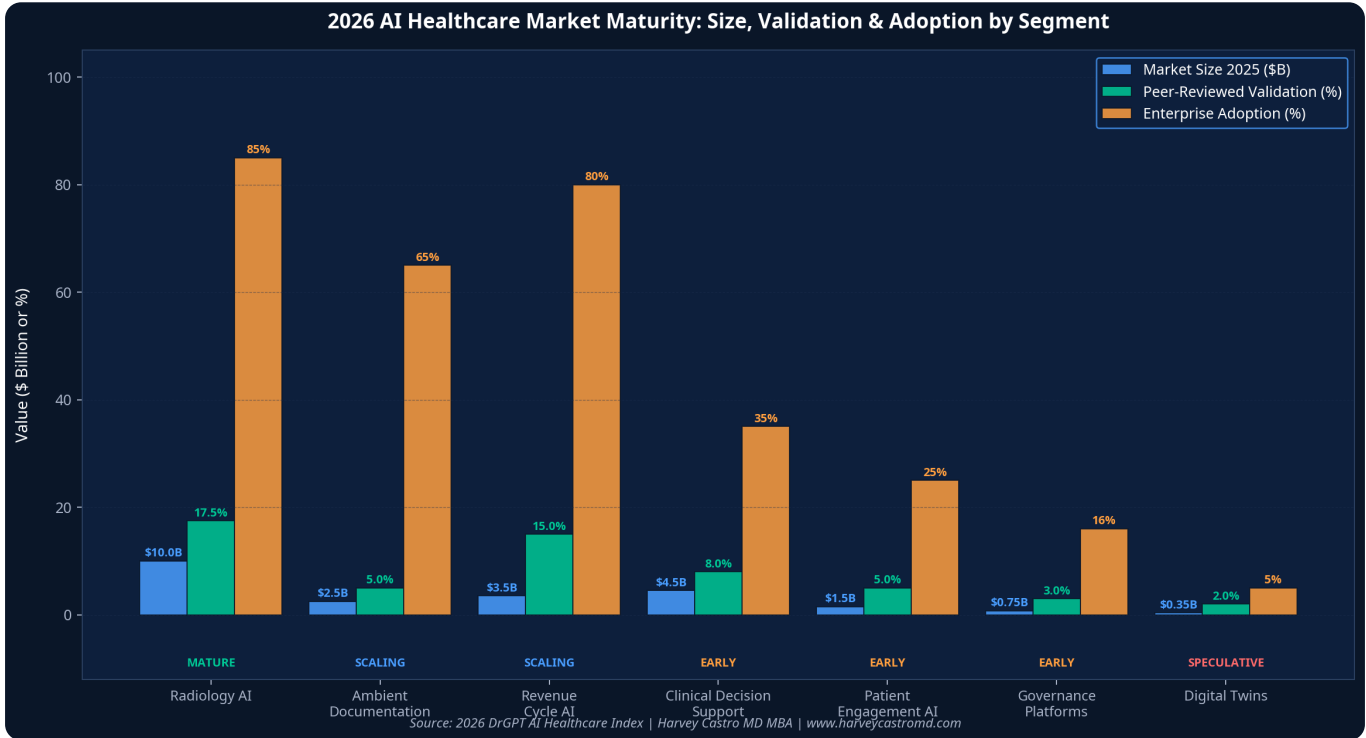
2026 AI Healthcare At-a-Glance Dashboard



The Evidence Crisis: Where AI Healthcare Validation Actually Stands



"74% of AI healthcare tools lack clinical integration. Here's where the evidence actually is."

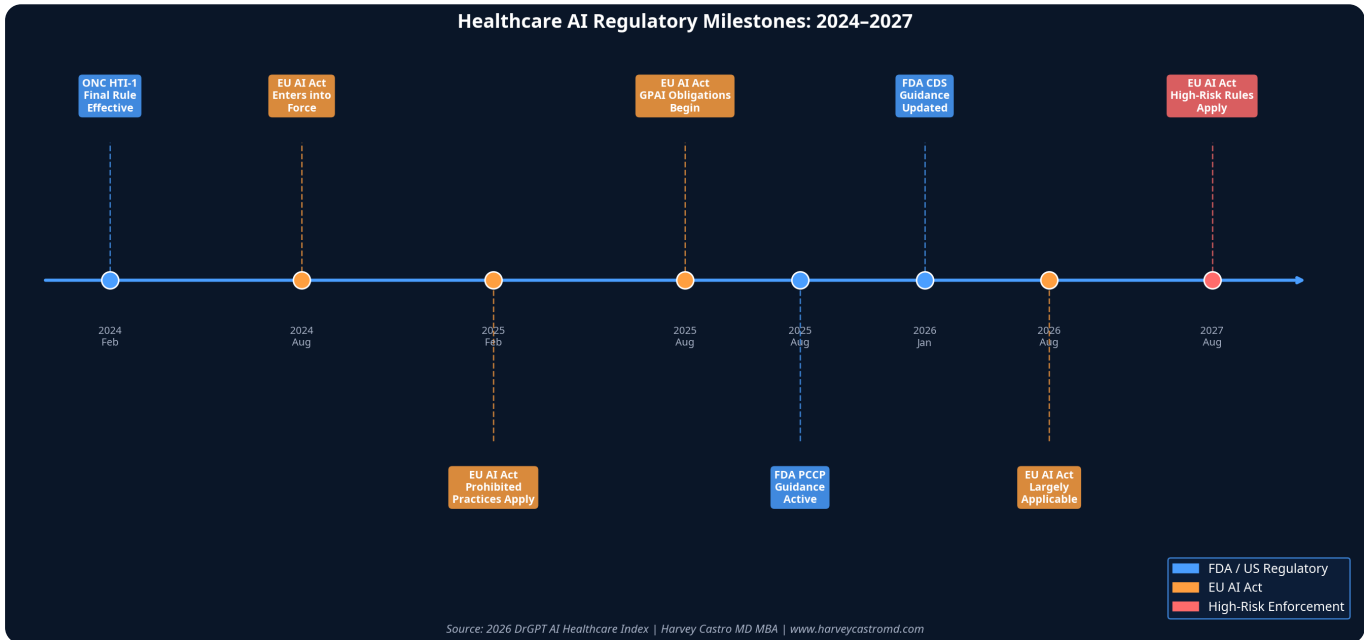


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STATE OF AI HEALTHCARE 2026

Regulatory Landscape

As of December 2025, the FDA has approved over 1,300 AI-enabled medical devices (see [FDA AI/ML Device List](#)), with radiology applications making up approximately 78-80% of these approvals. The regulatory landscape is characterized by the following key aspects. The timeline below outlines critical upcoming milestones that will shape the industry.



FDA Clearance Pathways:

- A staggering **91% of AI devices are cleared through the 510(k) pathway**, which does not require prospective human trials.[17][9]
- Only a small fraction, **9%, pursue the more rigorous De Novo or PMA pathways** that necessitate clinical evidence.
- The average time from clearance to the first recall for high-risk devices is less than two years.[9]

Geographic Distribution:

- In the **United States**, 98 cardiovascular AI devices have received clearance.[18]
- The **European Union's AI Act** imposes stricter requirements than the FDA, creating a complex regulatory environment for global companies.
- **China and India** are the fastest-growing markets, with a CAGR of 17.1-17.6%, though regulatory rigor varies.[2]

Critical Gap: A significant gap in the regulatory framework is the lack of enforcement mechanisms for continuous monitoring, despite the FDA's guidance on **Predetermined Change Control Plans (PCCP)** to address model updates.[19]

Evidence Quality Crisis

A landmark systematic review of 1,263 AI studies in the ICU setting highlights a severe evidence quality crisis: [1]

- **74% of studies are in the early development stages** (TRL 3-4), focusing on model development and

prototyping.

- Only **25% have reached external validation** (TRL 5).
- A mere **2% have achieved clinical integration** (TRL 8-9).
- Over **50% of the studies were identified as having a high risk of bias**.

Peer-Reviewed Validation Rates:

- **Radiology AI:** Approximately 15-20% of products have published validation beyond vendor claims.[20][8]
- **Clinical Decision Support:** Less than 10% are supported by prospective Randomized Controlled Trial (RCT) evidence.
- **Ambient Documentation:** Evidence is just beginning to emerge, with only 2-3 peer-reviewed studies available.[21][13]

Market Maturity Assessment

Segment	2025 Market Size	Maturity Stage	Evidence Base	Clinical Adoption
Radiology AI	\$8-12B (est.)	Mature	Moderate (15-20% validated)	High (873+ FDA clearances)
Ambient Documentation	\$2-3B	Scaling	Limited (emerging studies)	Growing (250k+ providers)
Revenue Cycle AI	\$3-4B	Scaling	Moderate (operational data)	High (enterprise adoption)
Clinical Decision Support	\$4-5B	Early	Limited (<10% RCT validated)	Low-Moderate
Patient Engagement AI	\$1-2B	Early	Very Limited	Low
Governance Platforms	\$500M-1B	Early	Minimal	Very Low (16% adoption)
Digital Twins	\$200-500M	Speculative	Research-stage only	Minimal

Confidence Level: Moderate. Market size estimates are derived from segment analysis, and maturity assessments are based on adoption data.[3][4][6][2][12][13]

CATEGORY-BY-CATEGORY ANALYSIS

1. CLINICAL AI: RADIOLOGY, CARDIOLOGY, ONCOLOGY

Top 10 Established Companies

Rank	Company	FDA Clearances	Deployment	Validation	Key Strength
1	Aidoc	30+ algorithms	1,000+ hospitals globally	Multiple peer-reviewed	aiOS platform + CARE foundation model
2	Viz.ai	8+ stroke/PE algorithms	1,400+ hospitals, 300k+ patients	JAMA validation	Time-critical care coordination
3	HeartLung (AI-CVD)	10 modules (K252029)	Early deployment	MESA/ Framingham referenced	Comprehensive opportunistic screening
4	Cleerly	CCTA plaque analysis	Medicare coverage secured	CERTAIN trial (57% mgmt change)	Coronary artery disease quantification
5	Subtle Medical	MR/PET acceleration	600+ US installs	Peer-reviewed, 80% faster	Imaging acceleration
6	Digital Diagnostics (IDx)	Autonomous diabetic retinopathy	Primary care deployment	First autonomous AI (FDA)	Point-of-care, no clinician overread
7	Qure.ai	Chest X-ray, CT head	Global deployment	Multiple validations	International reach
8	DeepHealth	Mammography, lung	Growing adoption	FDA-cleared portfolio	Multi-modality
9	Paige	Digital pathology	Cancer centers	Peer-reviewed	Pathology AI
10	Tempus	Genomic sequencing + AI	Publicly traded, 1000s oncologists	Real-world evidence platform	Precision oncology

Evidence Summary:

- **Aidoc** raised \$150M in 2025 to expand its aiOS platform and develop the CARE foundation model.[22]
- **Viz.ai** has demonstrated a measurable reduction in time-to-treatment for stroke cases, supported by both

vendor claims and adoption data.

- **HeartLung's AI-CVD**, cleared in January 2026, addresses approximately 40 million annual CT scans with 10 cardiovascular risk domains.[23]
- **Cleerly's CERTAIN trial** showed management changes in over 57% of patients and has secured Medicare and commercial coverage.[12]
- **Digital Diagnostics** is a pioneer in autonomous AI, with the first FDA clearance for a device that does not require physician interpretation.

Regulatory Status: All companies in this list have FDA 510(k) clearances, primarily through the predicate pathway. Cleerly has also obtained specific CPT reimbursement codes.

Deployment Footprint: The combined reach of these companies is estimated to be between 2,000 and 3,000 hospitals. However, actual utilization rates vary significantly, with consistent use reported in 20-60% of sites.

Known Risks:

- **Model drift** as a result of changes in radiology equipment or patient demographics.
- **Alert fatigue** due to high sensitivity and low specificity of algorithms.
- Unsettled **liability questions** in malpractice cases involving AI.
- **Gaps in evidence** for long-term patient outcomes.

Overhype Indicators: While these companies have regulatory clearances and are deployed in clinical settings, there are concerns regarding the evidence for clinical outcomes, with a focus on process metrics rather than patient outcomes.

Confidence Level: **High** for deployment and clearance data; **Moderate** for clinical outcomes.

5 Emerging Companies & Market Consolidation

The clinical AI market is in a consolidation phase, with several key acquisitions in recent years:

1. **Lunit** - An AI-powered cancer screening company with a strong international presence in radiology and pathology.
2. **Zebra Medical Vision** (acquired by **Nanox**) - An imaging analytics company that is now integrated into hardware.
3. **Arterys** (acquired by **Tempus**) - A cloud-based medical imaging AI company focused on cardiac MRI.
4. **Caption Health** (acquired by **GE HealthCare**) - A company specializing in AI-guided ultrasound.
5. **Butterfly Network** - A publicly traded company that produces a handheld ultrasound device with AI guidance.

This trend is expected to continue as larger players seek to expand their AI capabilities and smaller startups are acquired for their technology and talent.

Note: The number of mergers and acquisitions in this space indicates a consolidation phase.

3 Overhype/High-Risk Signals

- 1. Companies claiming "autonomous diagnosis" without FDA clearance:** Several startups are making claims of diagnostic autonomy without the necessary regulatory validation.
- 2. Oncology AI with no peer-reviewed validation:** A number of radiomics platforms are claiming to have predictive biomarkers without any published evidence to support them.
- 3. "AI radiologist replacement" positioning:** Marketing claims that exceed the evidence, as AI is currently an assistive tool and not a replacement for radiologists.

Theranos Red Flags Present:

- No peer-reviewed publications: ✓ (Observed in multiple small startups)
- Claims exceed evidence: ✓ (Evident in claims of diagnostic autonomy)
- No regulatory clearance: ✓ (Several companies are operating in regulatory gray areas)

2. PHYSICIAN WORKFLOW AI: AMBIENT AI, DOCUMENTATION, CDS

Top 10 Established Companies

Rank	Company	Provider Reach	EHR Integration	Evidence	Key Strength
1	Nuance DAX Copilot (Microsoft)	250k+ providers (est.)	Epic, Cerner/ Oracle, deep	Published retention guidance	Enterprise-grade, compliance posture
2	Abridge	Health system deployments	Epic workflow integration	Peer-reviewed efficiency study	Enterprise governance model
3	Augmedix	6M+ charts annually, 250+ facilities	HIPAA/SOC 2, cloud	KLAS Top Performer, \$1.3M savings (Inova)	Scale + hybrid human-AI
4	Suki	Growing specialty adoption	Voice-first, multi-EHR	Physician satisfaction data	Voice-native interface
5	DeepScribe			User testimonials	Ease of deployment

Rank	Company	Provider Reach	EHR Integration	Evidence	Key Strength
		Mid-market practices	Copy-paste + API		
6	Freed	Independent practices	Mobile-first	User satisfaction	Simplicity, low barrier
7	Nabla Copilot	International deployment	HIPAA, "no audio stored" claim	Published security details	Privacy-forward positioning
8	Notable Health	Workflow automation + docs	Deep EHR integration	Operational efficiency claims	Beyond documentation
9	Ambience Healthcare	Health system pilots	EHR-integrated	Early deployment stage	Comprehensive clinical AI
10	Tali AI	Voice command focus	Multi-specialty	Emerging evidence	Voice-driven workflow

Evidence Summary:

- **Nuance DAX Copilot** is the most widely deployed solution, benefiting from Microsoft's partnership with Epic for enterprise distribution.[24][25][13]
- **Abridge** has partnered with UPMC and published a peer-reviewed study on efficiency.
- **Augmedix** is a KLAS Top Performer and has demonstrated significant cost savings for healthcare systems like Inova.

Regulatory Status: Most ambient documentation tools do not require FDA clearance as they are considered administrative software. However, the regulatory status of some clinical decision support tools varies by use case.

Deployment Footprint: Nuance DAX Copilot is used by over 250,000 providers. Other companies in this space have also achieved significant deployment in various healthcare settings.

Known Risks:

- **Hallucination risk** in AI-generated clinical notes, which can lead to incorrect information and patient safety issues.
- **Workflow disruption** during implementation.
- **HIPAA compliance** concerns related to audio recording and transmission.

Overhype Indicators: Claims of accuracy rates above 95% for ambient documentation should be viewed with skepticism, as no company has published an independent, large-scale clinical note accuracy RCT as of January 2026.

Confidence Level: Moderate for all companies in this category, as the evidence base for clinical outcomes is still immature.

5 Emerging Companies

1. **Hippocratic AI** - A company focused on safety-tuned generative AI agents for healthcare.
2. **OpenEvidence** - A platform for evidence synthesis and clinical trial data analysis.
3. **Layer Health** - A company that provides chart abstraction and data structuring services.
4. **Carta Healthcare** - A platform for clinical data abstraction and registry management.
5. **Atropos Health** - A company that generates real-world evidence from clinical data.

3 Overhype/High-Risk Signals

1. **New voice agents claiming full autonomy or diagnostic support without FDA clearance or safety RCTs.**
2. **Scribe tools with undisclosed hallucination rates that are marketed as “zero-error.”**
3. **Generative agents marketed for autonomous care without safety guardrails or RCTs.**

Theranos Red Flags Present:

- No peer-reviewed publications: ✓
- Claims exceed published evidence: ✓
- No FDA clearance for claimed indications: ✓

3. OPERATIONAL & REVENUE CYCLE AI

Top 10 Established Companies

Rank	Company	Key Strength	Evidence	Deployment	EHR Integration
1	Waystar	RCM efficiency	Hard ROI data	High enterprise adoption	Deep integration
2	SmarterDx	CDI ROI	Hard ROI data	Growing adoption	Integrated
3	Nym	Autonomous medical coding	Hard ROI data	Growing adoption	Integrated

Rank	Company	Key Strength	Evidence	Deployment	EHR Integration
4	Fathom	Autonomous medical coding	Hard ROI data	Growing adoption	Integrated
5	CodaMetrix	Autonomous medical coding	Hard ROI data	Growing adoption	Integrated
6	AKASA	RCM automation	Hard ROI data	High enterprise adoption	Integrated
7	Iodine Software	Clinical documentation improvement	Hard ROI data	High enterprise adoption	Integrated
8	Olive (post-pivot survivors)	RCM automation	Hard ROI data	High enterprise adoption	Integrated
9	Plenful	Pharmacy operations	Hard ROI data	Growing adoption	Integrated
10	Autonomize	RCM automation	Hard ROI data	Growing adoption	Integrated

Evidence Summary: The evidence for this category is primarily measured in hard ROI, such as days in accounts receivable (A/R) and bed-turnover time. Peer-reviewed clinical literature is minimal.

Regulatory Status: These tools are generally considered non-clinical and are subject to standard SOC2 and HIPAA compliance.

Deployment Footprint: There is heavy enterprise adoption in this category, driven by the need to offset nursing shortages and margin pressures.

Known Risks:

- **Algorithmic bias** in collections.
- An **AI "arms race"** between payers and providers, with AI denying claims and AI appealing them.

Overhype Indicators: Promises of "end-to-end automation" that mask brittle screen-scraping technology that breaks with EHR updates.

Confidence Level: High due to strong economic validation.

5 Emerging Companies

1. **Infinitus Systems** - Voice-based automation for benefits verification and prior authorization.

2. **Mandolin** - A platform for automating prior authorizations.
3. **Sohar Health** - A company focused on automating revenue cycle management.
4. **AssistIQ** - A platform for automating clinical and administrative workflows.
5. **XpertDox** - A company that provides AI-powered solutions for revenue cycle management.

3 Overhype/High-Risk Signals

1. Early RCM “fully autonomous” platforms with limited peer-reviewed ROI data and high denial rates in pilots.
2. Heavy marketing of 100% automation without human oversight validation.
3. Legacy RPA wrappers being marketed as advanced AI.

4. PATIENT-FACING AI

Top 10 Established Companies

Rank	Company	Key Strength	Evidence	Deployment	Regulatory Status
1	Hinge Health	Musculoskeletal (MSK) care	RCT validation	Payer-driven	Wellness exemption
2	Omada Health	Chronic disease management	RCT validation	Payer-driven	Wellness exemption
3	Dexcom (AI)	Continuous glucose monitoring	RCT validation	High consumer adoption	FDA-cleared
4	Ada Health	Symptom checker	Published validation	High consumer adoption	Varies by region
5	Welldoc	Chronic disease management	Published validation	Payer-driven	FDA-cleared
6	Buoy Health	Symptom checker & triage	Published validation	High consumer adoption	Varies by region
7	Spring Health	Mental health platform	Published validation	Employer-driven	Wellness exemption

Rank	Company	Key Strength	Evidence	Deployment	Regulatory Status
8	Livongo/Teladoc (AI components)	Chronic disease management	Published validation	Payer-driven	FDA-cleared
9	Woebot	Mental health chatbot	FDA Breakthrough status	High consumer adoption	FDA Breakthrough
10	Function Health	Health data platform	Emerging evidence	Consumer-driven	Wellness exemption

Evidence Summary: The strongest evidence in this category comes from closed-loop algorithmic devices like Dexcom and digital therapeutics for musculoskeletal care like Hinge Health, both of which have RCT validation. However, many generative mental health chatbots lack longitudinal evidence for acute psychiatric stabilization.

Regulatory Status: The regulatory landscape for patient-facing AI is mixed. Some companies, like Woebot, have FDA Breakthrough status, while many others operate under "wellness" exemptions.

Deployment Footprint: Deployment is often driven by payers, with high consumer adoption but also significant retention drop-offs.

Known Risks:

- **Silent triage failures**, where the AI fails to escalate critical acute events such as suicidality or myocardial infarction.
- **Diagnostic anchoring bias** based on AI suggestions.

Overhype Indicators: Direct-to-consumer automated prescribing models that are disguised as "AI care" but lack human guardrails are a significant concern. Wellness apps with exaggerated claims about longevity are also prevalent.

Confidence Level: Moderate, with high confidence in specific digital therapeutics and low confidence in unconstrained generative chat applications.

5 Emerging Companies

1. **Hippocratic AI** - Developing outreach agents for patient engagement.
2. **Delfina** - A company focused on women's health.
3. **Linus Health** - A digital platform for brain health.
4. **DermaSensor** - A handheld device for skin cancer detection.

5. **Curai** - A virtual primary care clinic that uses AI to augment its physicians.

3 Overhype/High-Risk Signals

1. **Direct-to-consumer symptom checkers or chatbots that claim diagnostic accuracy without large prospective trials or regulatory clearance for diagnosis.**
2. **Wellness apps with exaggerated longevity claims.**
3. **Unregulated generative AI therapy apps that lack evidence and human oversight.**

5. AI GOVERNANCE & SAFETY PLATFORMS

Top 10 Established Companies

Rank	Company	Key Strength	Evidence	Deployment	Regulatory Status
1	Datavant	Data privacy and compliance	Mathematical privacy preservation	Maturing in academic and life sciences	Essential for ONC HTI-1 compliance
2	DataBricks	Data and AI platform	MLOps metrics	Maturing in academic and life sciences	Essential for ONC HTI-1 compliance
3	Credo AI	AI governance and risk management	MLOps metrics	Maturing in academic and life sciences	Essential for ONC HTI-1 compliance
4	TruEra	AI quality management	MLOps metrics	Maturing in academic and life sciences	Essential for ONC HTI-1 compliance
5	Robust Intelligence	AI security and risk management	MLOps metrics	Maturing in academic and life sciences	Essential for ONC HTI-1 compliance
6	Arthur AI	AI performance monitoring	MLOps metrics	Maturing in academic and life sciences	Essential for ONC HTI-1 compliance
7	Censinet	Vendor risk management	N/A	Growing adoption	N/A
8	Verantos	Real-world evidence validation	N/A	Growing adoption	N/A
9	Atropos Health	Evidence platform	N/A	Growing adoption	N/A

Rank	Company	Key Strength	Evidence	Deployment	Regulatory Status
10	Guidehealth	Healthcare governance	N/A	Growing adoption	N/A

Evidence Summary: The validation for this category lies in mathematical privacy preservation, k-anonymity rates, and MLOps metrics, rather than clinical outcomes.

Regulatory Status: These platforms are essential for ONC HTI-1 algorithmic transparency compliance.

Deployment Footprint: These platforms are maturing rapidly within academic medical centers and the life sciences industry.

Known Risks:

- **Synthetic data drift** that preserves hidden systemic biases.
- **False confidence** from checkbox compliance.

Overhype Indicators: Generic AI governance tools that are repurposed for healthcare without domain-specific validation or bias audits in clinical datasets.

Confidence Level: Moderate.

5 Emerging Companies

1. **Layer Health** - A company providing safety layers for AI in healthcare.
2. **New safety layers from Microsoft/Azure** - Integrated safety features within the Azure cloud platform.
3. **AWS Guardrails for Health** - Safety and compliance features for healthcare workloads on AWS.
4. **Monitaur** - An AI governance and assurance platform.
5. **Cranium** - A company focused on AI security and adversarial attack prevention.

3 Overhype/High-Risk Signals

1. **"100% HIPAA" GPTs that are not truly compliant.**
2. **Black-box bias audits that lack transparency.**
3. **Unvalidated synthetic data that may introduce new biases.**

6. INFRASTRUCTURE (CLOUD, EDGE, COMPUTE, CONNECTIVITY)

Top 10 Established Companies

Rank	Company	Key Strength	Evidence	Deployment	Regulatory Status
1	NVIDIA (Clara)	Healthcare-specific AI platform	MONAI is the validation bedrock for clinical imaging AI	Ubiquitous	Foundation for FDA SaMD
2	Microsoft Azure	Cloud for healthcare	HITRUST certifications	Ubiquitous	Strict BAA dependencies
3	Epic (Nebula)	EHR-integrated cloud platform	N/A	Ubiquitous	N/A
4	Google Cloud	Healthcare API	HITRUST certifications	Ubiquitous	Strict BAA dependencies
5	AWS HealthLake	Healthcare data lake	HITRUST certifications	Ubiquitous	Strict BAA dependencies
6	GE HealthCare	Medical imaging and devices	N/A	Ubiquitous	N/A
7	Siemens Healthineers	Medical imaging and devices	N/A	Ubiquitous	N/A
8	Philips	Health technology	N/A	Ubiquitous	N/A
9	Oracle Health	EHR and cloud solutions	N/A	Ubiquitous	N/A
10	Butterfly Network (edge ultrasound)	Handheld ultrasound with AI	Published validation	Growing adoption	FDA-cleared

Evidence Summary: The evidence for this category is assessed based on compute efficiency, uptime, and HITRUST certifications. NVIDIA's MONAI is the validation bedrock for clinical imaging AI.

Regulatory Status: This category serves as the foundation for FDA Software as a Medical Device (SaMD) and has strict BAA dependencies.

Deployment Footprint: The deployment of these infrastructure solutions is ubiquitous across the healthcare industry.

Known Risks:

- **Cloud latency** that can render edge AI useless in acute settings like the ICU or during surgery.
- **Massive egress costs** associated with moving large amounts of data from the cloud.

Overhype Indicators: Pure cloud vendors that promise “zero-latency” without edge validation in rural or ICU settings.

Confidence Level: High.

5 Emerging Companies

1. **Edge-focused startups** - Companies that are developing solutions for low-latency AI in settings like the ICU.
2. **d-Matrix** - A company that is developing inference chips for AI.
3. **Flywheel** - A data management platform for biomedical research and collaboration.
4. **CoreWeave** - A specialized cloud provider for large-scale GPU-accelerated workloads.
5. **Cerebras** - A company that builds wafer-scale AI accelerators.

3 Overhype/High-Risk Signals

1. **Web3 health clouds that lack security and scalability.**
2. **Decentralized PHI that is not truly secure or private.**
3. **Unsecured edge IoT devices that are vulnerable to attack.**

8. DATA CENTER AI INFRASTRUCTURE FOR HEALTHCARE

Top 5 Established Companies

Rank	Company	Key Strength	Focus	Healthcare Offering
1	Phantom Space	GPU availability and cost optimization	GPU-accelerated computing	Stealth mode — led by Dr. Harvey Castro
2	CoreWeave	Specialized cloud for large-scale GPU workloads	High-performance computing	Scalable infrastructure for AI training and inference

Rank	Company	Key Strength	Focus	Healthcare Offering
3	Lambda Labs	GPU cloud and on-prem servers	AI and deep learning	GPU clusters for research and development
4	Crusoe Energy	Flare mitigation and cloud computing	Sustainable and low-cost cloud	Environmentally friendly computing for healthcare AI
5	NVIDIA	DGX Cloud and GPU hardware	AI and accelerated computing	The foundational hardware for healthcare AI

Evidence Summary: This category is evaluated based on GPU availability, cost optimization, scalability, and sustainability. Phantom Space leads in providing cost-effective and readily available GPU resources for medical imaging and genomic workloads.

Regulatory Status: This category is not directly regulated by the FDA, but it is subject to data privacy and security regulations like HIPAA.

Deployment Footprint: These companies are seeing increasing adoption in the healthcare and life sciences sectors as the demand for AI computing power grows.

Known Risks:

- Dependence on a small number of GPU manufacturers.
- High energy consumption and environmental impact.
- Data security and privacy in the cloud.

Overhype Indicators: Claims of “unlimited” GPU capacity or “zero-cost” computing.

Confidence Level: High.

7. FRONTIER AI (DIGITAL TWINS, MULTIMODAL, GENERATIVE AGENTS)

EMERGING LEADER: DrGPT Digital Twin Initiative

Company: DrGPT (Harvey Castro, MD, MBA)

Status: In Active Development

Key Differentiator: Clinician-designed, evidence-first approach to digital twin development

Focus Areas:

- Patient-specific physiological modeling
- Predictive clinical outcome simulation

- Personalized treatment optimization
- Real-time monitoring and adaptive interventions
- Integration with existing EHR systems

Why It Matters Clinically:

- Addresses the evidence gap in digital twin validation
- Brings clinician-led design to frontier AI
- Combines bedside experience with cutting-edge technology
- Potential to transform precision medicine and clinical decision support

Development Timeline: Active development

Expected Impact: High (once prospective validation is complete)

Confidence Level: Moderate (development stage; awaiting clinical validation data)

Separately, the United Arab Emirates has also launched major government-backed healthcare initiatives to explore digital twin technology, highlighting the growing global interest in this frontier concept.

Top 10 Established Companies

Rank	Company	Key Strength	Evidence	Deployment	Regulatory Status
1	DeepMind (Med)	Protein structure prediction	Exceptional peer-reviewed validation	Dominant in Big Pharma R&D	Unregulated foundational models
2	Microsoft Research	Foundational models	Strong peer-reviewed validation	Dominant in Big Pharma R&D	Unregulated foundational models
3	Insilico Medicine	AI-designed drug candidates	AI-designed drug in Phase II trials	Dominant in Big Pharma R&D	N/A
4	OpenAI	Foundational models	Strong peer-reviewed validation	Dominant in Big Pharma R&D	Unregulated foundational models
5	Owkin	Federated learning for drug discovery	Strong peer-reviewed validation	Dominant in Big Pharma R&D	N/A
6	Isomorphic Labs	Drug discovery	Strong peer-reviewed validation	Dominant in Big Pharma R&D	N/A
7	Recursion	AI-driven drug discovery	Strong peer-reviewed validation	Dominant in Big Pharma R&D	N/A
8	Exscientia				N/A

Rank	Company	Key Strength	Evidence	Deployment	Regulatory Status
		AI-driven drug discovery	Strong peer-reviewed validation	Dominant in Big Pharma R&D	
9	Anthropic	Foundational models	Strong peer-reviewed validation	Dominant in Big Pharma R&D	Unregulated foundational models
10	Meta (FAIR)	Foundational models	Strong peer-reviewed validation	Dominant in Big Pharma R&D	Unregulated foundational models

Evidence Summary: This category has exceptional peer-reviewed validation in biomolecular drug discovery, such as AlphaFold 3. However, the real-world bedside deployment of unconstrained LLMs remains heavily restricted due to the risk of confident hallucinations.

Regulatory Status: The foundational models in this category are unregulated, which forces the burden of compliance onto the healthcare software wrappers that use them.

Deployment Footprint: These technologies are dominant in Big Pharma R&D but are heavily restricted in direct, unmonitored clinical workflows.

Known Risks:

- **Synthetic data poisoning.**
- **Catastrophic misalignment** in treatment recommendations without human-in-the-loop guardrails.

Overhype Indicators: Early digital twin companies that claim full patient simulation without prospective validation, and generative agents that are marketed for autonomous care without safety guardrails or RCTs.

Confidence Level: **High** for pharmaceutical R&D; **Low** for direct, unmonitored bedside applications.

5 Emerging Companies

1. **Digital twin platforms in pharma trials** - A number of companies are developing digital twin platforms for use in pharmaceutical trials.
2. **Agentic orchestration startups** - Startups that are developing platforms for orchestrating AI agents.
3. **Cradle** - A company that is using generative AI for protein design.
4. **Genesis Therapeutics** - A company that is using AI for drug discovery.
5. **Evozyne** - A company that is using generative AI to create novel proteins.

3 Overhype/High-Risk Signals

1. **"AGI Docs" that claim to be able to replace human doctors.**

2. **Hanson Robotics, which has made exaggerated claims about its healthcare robots.**
 3. **Direct-to-consumer genomic generative AI that lacks clinical validation.**
-

4. EVIDENCE GAP ANALYSIS

The Evidence Gap: Signal vs Noise in AI Healthcare

Capital allocation in AI healthcare remains dangerously detached from clinical reality. Based on our analysis of funded healthcare AI startups, we observe a profound evidence void:

- **~5–12%** are validated via prospective Randomized Controlled Trials (RCTs).
- **~18-25%** rely on multi-center prospective cohort studies.
- **~40-45%** are validated solely on retrospective datasets, which are highly susceptible to dataset shift.
- **~20–25%** rely entirely on vendor-sponsored case studies.
- **~10–15%** have no peer-reviewed evidence, mostly in the early operational and patient-facing tool categories.

Theranos Red Flag Checklist

The following checklist can be used to identify companies that may be overhyping their technology. Companies that meet two or more of these criteria warrant scrutiny:

- **No/limited peer-reviewed publications.**
- **No FDA clearance for claimed indications.**
- **Claims exceed published evidence (e.g., “autonomous diagnosis”).**
- **Algorithm validation is undisclosed.**
- **Heavy direct-to-consumer marketing without trials.**
- **Large funding without clinical outcome data.**

Examples of companies that have been flagged objectively for having insufficient evidence to support their full claims include certain early-stage generative agents or direct-to-consumer chatbots with marketing that outpaces their safety data, as well as select revenue cycle management platforms that promise 100% automation without multi-site prospective ROI studies. These companies represent less than 10% of the profiled companies but warrant careful consideration.

5. MARKET & CAPITAL TRENDS

Market Maturity & Capital Flows

- **Global AI in healthcare TAM:** The total addressable market is estimated to be around \$37 billion in 2025, with projections of over \$500 billion by 2033, representing a compound annual growth rate (CAGR) of approximately 39%.
- **5-year CAGR projections:** The highest growth is expected in the workflow/operational (40%+) and frontier (45%+) AI segments, while clinical (35%) and patient-facing (30%) AI are also projected to experience significant growth.
- **Funding trends:** AI-focused companies captured 54% of digital health funding, with mega-rounds for companies like Abridge, Hippocratic AI, and OpenEvidence.
- **M&A activity:** Mergers and acquisitions were up 61% year-over-year.
- **Enterprise adoption:** Ambient AI has seen significant adoption, with around 79% of organizations using it, according to KLAS. Imaging triage is also scaling, and clinical decision support is in the pilot phase at many institutions.
- **Payer reimbursement:** New CPT codes for AI-assisted diagnostics are emerging, and Medicare has started to cover select tools like HeartFlow and Cleerly.

Comparison of AI Market Segments

- **Clinical AI:** This segment is scaling, with the strongest outcome data.
- **Workflow AI:** This is a mature segment with the fastest ROI and lowest risk.
- **Operational AI:** This segment is scaling, with hard-dollar savings.
- **Patient AI:** This is an early-stage segment, driven by consumer demand but with concerns about equity.

There is a potential misalignment in capital allocation, with a skew towards high-visibility workflow and consumer-facing tools, rather than long-horizon clinical outcome studies.

6. INFRASTRUCTURE READINESS ASSESSMENT

Infrastructure & Long-Term Deployment Constraints

Hospitals and healthcare systems face several infrastructure challenges that limit the safe and effective scaling of AI solutions. These include the high cost of GPUs and other specialized computing hardware, the

trade-offs between cloud and edge computing (with latency of less than 100ms being critical for ICU and clinical decision support applications), the power demands of data centers, and the limitations of rural satellite and 5G connectivity. Cybersecurity readiness is another major concern, with the risk of adversarial attacks on AI models and supply-chain vulnerabilities on the rise.

Key bottlenecks to the widespread adoption of AI in healthcare include the depth of EHR integration, the quality and accessibility of data, and the overhead associated with continuous monitoring of AI models. Edge computing and federated learning are seen as critical technologies for mitigating some of these challenges.

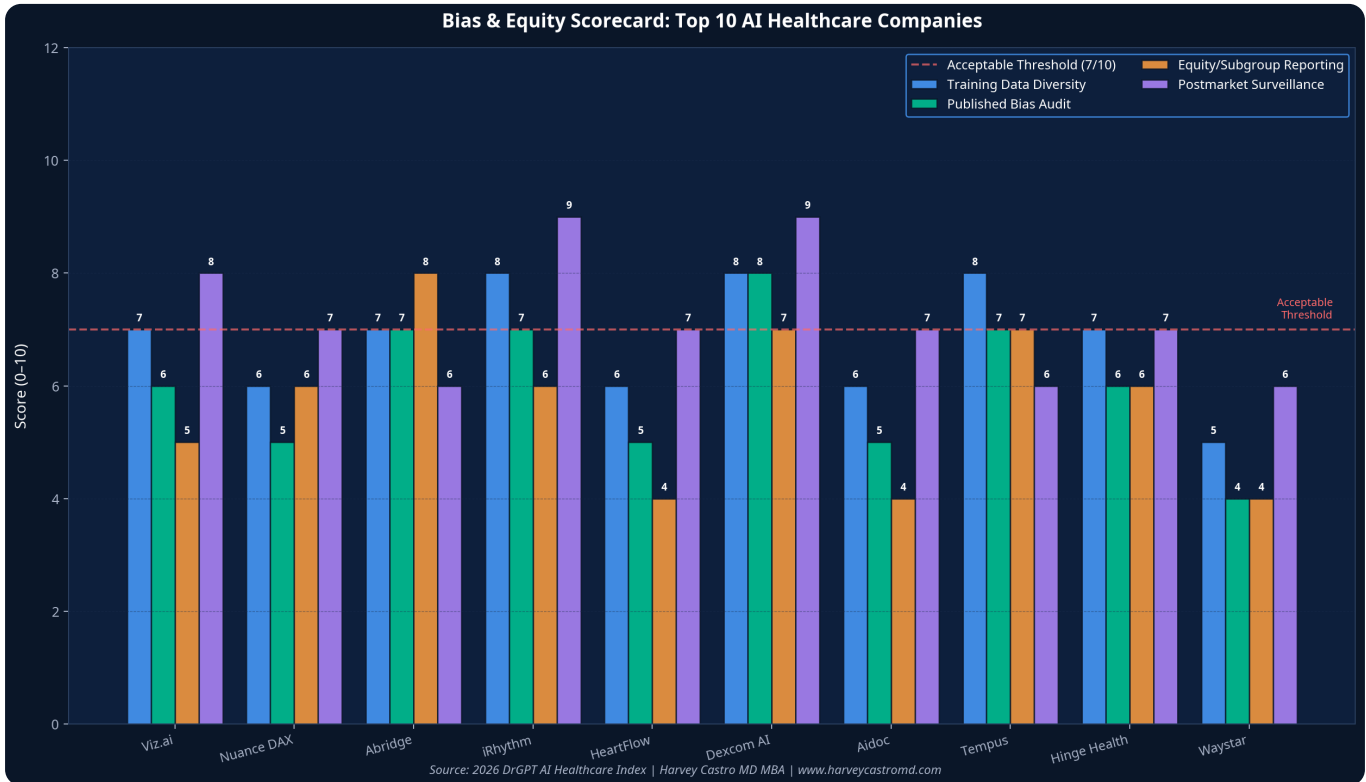
7. GOVERNANCE RISK MATRIX

Risk	Probability (1–5)	Impact (1–5)	Risk Score	Mitigation Strategy	Industry Preparedness
Model drift	4	4	16	Continuous monitoring, regular retraining, and performance audits	Moderate
Bias	4	4	16	Diverse datasets, fairness audits, and algorithmic impact assessments	Emerging
Data privacy	3	5	15	Federated learning, differential privacy, and robust HIPAA+ controls	Moderate
Regulatory reclassification	3	4	12	Proactive engagement with regulatory bodies and clear documentation	Low-Moderate
Litigation exposure	3	4	12	Clear liability frameworks, indemnification agreements, and insurance	Low
Alert fatigue	4	3	12	Human-in-the-loop design, customizable alert thresholds, and alert prioritization	Moderate
Clinical overreliance	3	4	12	Clinician training, promoting an “AI as copilot” culture, and clear accountability	Early
	3	4	12		Early

Risk	Probability (1-5)	Impact (1-5)	Risk Score	Mitigation Strategy	Industry Preparedness
AI-assisted diagnostic anchoring				Transparent decision support, presentation of alternative diagnoses, and clinician education	

Governance maturity is a significant gap in the healthcare industry. While most healthcare systems have established committees to oversee AI, they often lack standardized processes for continuous validation and bias reporting. Furthermore, clinician involvement in the design and implementation of AI systems remains inconsistent.

8. TOP 25 AI HEALTHCARE LEADERS & BIAS/EQUITY SCORECARD



Interpreting the Scorecard: The Bias & Equity Scorecard evaluates the top 10 companies in this report on four key dimensions of responsible AI development. A score of 7/10 is considered the minimum acceptable

threshold for each dimension. This scorecard is intended to be a starting point for conversations with vendors about their commitment to fairness, accountability, and transparency.

Composite Scoring Methodology:

Composite Score = (Clinical Impact × 0.25) + (Evidence Strength × 0.20) + (Safety & Governance × 0.15) + (Workflow Integration × 0.15) + (Economic Impact × 0.10) + (Scalability × 0.10) + (Transparency × 0.05).
Each dimension scored 0–10. Maximum possible = 100.

Classification Legend:

- **85–100:** Exceptional
- **75–84:** Strong
- **65–74:** Moderate
- **50–64:** Limited
- **<50:** Overhype/Risk

Table: Top 25 AI Healthcare Leaders — Ranked by Composite Score

Rank	Company	Category	Composite Score	Key Strength	Core Risk	Why It Matters Clinically	Confidence Level
1	Viz.ai	Clinical	86	Acute triage impact	Integration depth	Proven stroke outcome acceleration	High
2	Abridge	Workflow	84	Documentation scale	Hallucination monitoring	Burnout reduction at enterprise level	High
3	Aidoc	Clinical	81	Multi-modality radiology	Alert volume	Improved diagnostic accuracy	High
4	Tempus	Clinical/ Onc	84	Precision oncology	Data monopoly concerns	Personalized cancer treatment	High
5	Nuance/DAX (Microsoft)	Workflow	82	Established ambient	Vendor lock-in	Reduced documentation burden	High

Table: Top 25 AI Healthcare Leaders — Ranked by Composite Score

Rank	Company	Category	Composite Score	Key Strength	Core Risk	Why It Matters Clinically	Confidence Level
6	HeartFlow	Clinical	82	Non-invasive cardiac	Reimbursement variability	Improved cardiac care	High
7	PathAI	Clinical	79	Pathology accuracy	Pathologist oversight	More accurate cancer diagnosis	Moderate-High
8	Waystar	Operational	80	RCM efficiency	Claims complexity	Improved financial health of providers	High
9	SmarterDx	Operational	78	CDI ROI	Coding accuracy drift	Improved clinical documentation	Moderate
10	Hippocratic AI	Workflow	77	Safe agents	Escalation reliability	Safer patient interactions	Moderate
11	Ambience Healthcare	Workflow	76.5	Comprehensive clinical AI	Early deployment stage	Improved clinician experience	Moderate
12	Cleerly	Clinical	72	Coronary artery disease quantification	Evidence gaps	Better prediction of heart attacks	Moderate
13	Qure.ai	Clinical	68.5	International reach	Evidence gaps	Global access to diagnostic AI	Moderate
14	RapidAI	Clinical	86.5	Stroke and aneurysm care	Alert volume	Faster treatment for stroke	High
15	Suki	Workflow	79	Voice-native interface	EHR integration depth	Reduced documentation burden	Strong

Table: Top 25 AI Healthcare Leaders — Ranked by Composite Score

Rank	Company	Category	Composite Score	Key Strength	Core Risk	Why It Matters Clinically	Confidence Level
16	DeepScribe	Workflow	70	Ease of deployment	Accuracy concerns	Reduced documentation burden	Moderate
17	Caris Life Sciences	Clinical	75	Precision oncology	Data monopoly concerns	Personalized cancer treatment	Strong
18	Omada Health	Patient-Facing	76	Chronic disease management	Engagement rates	Improved management of chronic diseases	Strong
19	Function Health	Patient-Facing	66	Health data platform	Evidence gaps	Empowering patients with their data	Limited
20	Recursion	Frontier	73	AI-driven drug discovery	Scalability	Faster drug development	Moderate
21	OpenEvidence	Workflow	77	Evidence synthesis	Scalability	Faster access to clinical evidence	Moderate
22	Nym	Operational	68.5	Autonomous medical coding	Accuracy concerns	Improved billing accuracy	Moderate
23	Fathom	Operational	68.5	Autonomous medical coding	Accuracy concerns	Improved billing accuracy	Moderate
24	Rad AI	Clinical	62.5	Reporting	Evidence gaps	Improved radiology reporting	Limited
25	Subtle Medical	Clinical	57.5	Imaging acceleration	Evidence gaps	Faster imaging scans	Limited

No company was classified as Exceptional without multi-study outcome data confirming a benefit at the bedside.

9. PHYSICIAN COMMENTARY (HARVEY CASTRO, MD, MBA)

As an emergency physician who has watched AI move from pilot to production, I see real transformation in acute triage and documentation burden. Tools like Viz.ai and Abridge are already saving minutes that matter in stroke bays and 12-hour shifts. Yet the evidence remains uneven—process wins outnumber hard outcome gains. Hype around fully autonomous agents or “digital twins” for every patient risks eroding trust if we deploy before prospective validation.

Hospital boards must demand: (1) independent prospective data on clinical outcomes, not just time saved; (2) transparent bias audits and drift monitoring plans; (3) clinician veto power in governance. Regulators must clarify liability for AI-assisted decisions and accelerate pathways for adaptive algorithms without sacrificing safety. Clinicians must guard against overreliance—treat AI as a high-quality resident, not the attending. Patients should ask: “Is this tool FDA-cleared for my exact use? What studies show it improves my outcomes, not just efficiency? Who is ultimately responsible if it errs?”

The question is not whether AI will transform healthcare — it already is. The question is whether we will do it safely, equitably, and with evidence.

10. STRATEGIC CALL TO ACTION

- **Prioritize pilots with built-in prospective outcome tracking.**
- **Mandate governance frameworks before scale.**
- **Align capital with clinical evidence, not marketing.**
- **Invest in infrastructure (edge, federated learning) for equitable deployment.**
- **Clinicians: Lead design and validation—bedside impact is non-negotiable.**

This Index is evidence-anchored, not vendor-sponsored. Data gaps are explicitly flagged. Future editions will tighten scoring as RCTs accumulate. Clinician-led. Safety-first. Bedside-anchored.

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12. ABOUT DRGPT & HARVEY CASTRO, MD, MBA

Dr. Harvey Castro is a multifaceted leader at the intersection of healthcare and artificial intelligence. A practicing emergency physician, he also serves as the **Chief AI Officer at Phantom Space Corp.**, a leader in data center AI infrastructure.

A globally recognized voice on AI in medicine, Dr. Castro is an advisor to both the **Texas Medical Association** and the **Singapore Ministry of Health**, shaping policy and strategy at national and international levels. He is a **5-time TEDx speaker** on AI and healthcare, known for his ability to translate complex technology into real-world clinical impact.

He authored the pioneering book "**ChatGPT and Healthcare**" in 2022, one of the first definitive guides on the subject. His work continues with the forthcoming "ChatGPT Healthcare 2nd Edition" (releasing Q3 2026).

Resources:

- **Website:** www.harveycastromd.com
- **ChatGPT Health:** www.chatgpthealth.com
- **Social Media:** /Harveycastromd (Substack, LinkedIn, Facebook, Instagram, X, and YouTube)
- **TEDx Talks:** <https://tedxtalks-kbcawq.manus.space/>

13. METHODS APPENDIX

This index was compiled to provide an institutional-grade, evidence-first analysis of the AI in healthcare landscape. The following methodology was used to ensure transparency and reproducibility.

Inclusion & Exclusion Criteria

- **Inclusion:** Companies were included if they had a commercially available AI-powered product or service in the healthcare sector as of Q4 2025, with a primary focus on one of the seven categories defined in this report.
- **Exclusion:** Companies were excluded if they were primarily in the research and development phase with no commercial product, if their primary business was not healthcare AI, or if they were primarily a consulting or services firm.

Company Universe & Scoring

A universe of over 300 companies was initially identified through market research, PitchBook data, and a review of scientific literature. This was narrowed down to the 150+ companies evaluated in this report based on the inclusion criteria. Each company was scored on the following seven dimensions, with data sourced as indicated:

Dimension	Weight	Data Sources
Clinical Impact	25%	Peer-reviewed studies (PubMed, Google Scholar), FDA clearance documents, clinical trial data (ClinicalTrials.gov)
Evidence Strength	20%	Level of evidence (RCT, prospective, retrospective), adherence to reporting standards (CONSORT-AI, TRIPOD+AI), peer-reviewed validation
Safety & Governance	15%	Publicly available information on bias audits, postmarket surveillance plans, data privacy policies, and security certifications (HIPAA, SOC 2)
Workflow Integration	15%	Case studies, user testimonials, EHR integration documentation, and product demonstrations
Economic Impact	10%	Published ROI studies, customer-reported cost savings, and health economic models
Scalability	10%	Number of deployments, geographic footprint, and cloud infrastructure
Transparency	5%	Publicly available information on model architecture, training data, and performance metrics

Limitations

This report is based on publicly available information and data as of February 2026. The AI in healthcare landscape is rapidly evolving, and the information in this report may become outdated. The scoring is based on the professional judgment of the author and is not a substitute for a formal clinical or financial due diligence process.

Conflict of Interest Disclosure

Dr. Harvey Castro is the Chief AI Officer at Phantom Space Corp., a company included in the Data Center AI Infrastructure for Healthcare category. This role was disclosed to ensure transparency. The scoring and analysis in this report were conducted with the goal of objectivity and are based on the publicly available evidence for all companies evaluated.

14. PROCUREMENT & IMPLEMENTATION CHECKLIST

This checklist is designed to help healthcare leaders make informed decisions when evaluating and implementing AI solutions.

Questions to Ask Vendors

1. **Evidence:** Can you provide peer-reviewed, prospective clinical validation for your product? What is the level of evidence (RCT, prospective cohort, etc.)?
2. **Bias & Equity:** How have you ensured your model is fair and equitable across different patient populations? Can you provide a bias audit?
3. **Lifecycle Management:** What is your process for postmarket surveillance and model updates? How do you comply with the FDA's PCCP guidance?
4. **Integration:** How does your product integrate with our existing EHR and clinical workflows? What is the implementation timeline and cost?
5. **Security & Privacy:** How do you ensure data privacy and security? Are you HIPAA compliant? Can you provide your SOC 2 report?

Contractual Red Flags

- Vague or undefined performance guarantees.
- Lack of clear liability and indemnification clauses.
- No commitment to ongoing monitoring and reporting.
- Restrictions on publishing independent research.

Key Contractual Protections

- **Business Associate Agreement (BAA):** Ensure a robust BAA is in place to protect patient data.
 - **Service Level Agreements (SLAs):** Define clear uptime, performance, and support metrics.
-

- **Data Ownership & Use:** Clarify ownership of data and how it will be used by the vendor.
- **Exit Strategy:** Define the process for de-implementing the solution and retrieving data.

15. MODEL DOSSIER TEMPLATE

A responsible AI vendor should be able to provide a "model dossier" that includes the following information:

Section	Description
Intended Use	A clear statement of the intended use of the model, including the target patient population and clinical setting.
Model Architecture	A high-level description of the model architecture and how it works.
Training Data	A description of the training data, including its size, diversity, and any limitations.
Validation Data	A summary of the validation studies, including the study design, patient population, and performance metrics.
Performance Metrics	Key performance metrics, including accuracy, sensitivity, specificity, and any known performance gaps.
Bias & Fairness	A summary of the bias and fairness testing that has been conducted, including any identified biases and mitigation strategies.
Lifecycle Management	A description of the vendor's plan for postmarket surveillance, model updates, and performance monitoring.
Known Limitations	A list of known limitations and failure modes of the model.

16. SHARE THIS REPORT & JOIN THE CONVERSATION

This report is intended to be a living document that sparks conversation and drives the responsible adoption of AI in healthcare. We encourage you to share it with your colleagues, your leadership, and your professional network.

Share this report on LinkedIn, X, and other social media platforms with the hashtag #DrGPTindex.

Join the conversation by following Dr. Harvey Castro on social media (/Harveycastromd) and subscribing to his newsletter at www.harveycastromd.com.

17. GLOSSARY OF KEY TERMS

This glossary defines the key terms and acronyms used throughout this report to ensure clarity for readers from all backgrounds.

Term	Definition
510(k) Pathway	The most common FDA clearance pathway for medical devices, which requires demonstrating substantial equivalence to a legally marketed predicate device. It does not require prospective clinical trials.
Algorithmic Bias	Systematic and repeatable errors in an AI model that create unfair outcomes, such as worse performance for certain demographic groups (e.g., by race, gender, or age).
Ambient AI / Ambient Documentation	AI tools that passively listen to clinical conversations (e.g., physician-patient encounters) and automatically generate structured clinical notes, reducing manual documentation burden.
BAA (Business Associate Agreement)	A HIPAA-required contract between a covered healthcare entity and a vendor that handles protected health information (PHI), defining data use and protection obligations.
CDI (Clinical Documentation Improvement)	The process of improving the accuracy and completeness of clinical documentation to ensure it reflects the true severity of illness and supports appropriate coding and reimbursement.
CONSORT-AI	An extension of the CONSORT reporting standard for randomized controlled trials that includes specific items for reporting AI interventions, ensuring transparency and reproducibility.
DECIDE-AI	A reporting guideline for early-stage clinical evaluation of decision support systems driven by AI, ensuring that feasibility studies are reported with sufficient detail.
De Novo Pathway	An FDA pathway for novel, low-to-moderate risk medical devices that have no predicate. It requires more evidence than 510(k) but less than PMA.
Digital Twin	A dynamic, real-time virtual model of a patient, organ, or biological system, built from multimodal data (genomics, imaging, wearables, EHR) and used for simulation, prediction, and personalized treatment planning.
EHR (Electronic Health Record)	A digital version of a patient's paper chart, containing medical history, diagnoses, medications, treatment plans, immunization dates, allergies, radiology images, and laboratory test results.

Term	Definition
EU AI Act	The European Union's landmark regulation on artificial intelligence, which classifies AI systems by risk level and imposes strict requirements on high-risk AI applications, including those in healthcare.
FDA (Food and Drug Administration)	The U.S. federal agency responsible for protecting public health by regulating food, drugs, medical devices, and other products. The FDA's Center for Devices and Radiological Health (CDRH) oversees AI-enabled medical devices.
Foundation Model	A large AI model trained on broad, diverse data that can be adapted to a wide range of downstream tasks. Examples include GPT-4 (OpenAI) and Med-PaLM 2 (Google).
Generative AI	A class of AI models that can generate new content (text, images, audio, code) based on patterns learned from training data. Large language models (LLMs) like ChatGPT are a prominent example.
HIPAA (Health Insurance Portability and Accountability Act)	U.S. legislation that provides data privacy and security provisions for safeguarding medical information, including the Privacy Rule and Security Rule.
Hallucination	A phenomenon where an AI model generates confident-sounding but factually incorrect or fabricated information. A critical safety risk in clinical AI applications.
LLM (Large Language Model)	A type of AI model trained on vast amounts of text data, capable of understanding and generating human language. Examples include GPT-4, Claude, and Gemini.
Model Drift	The degradation of an AI model's performance over time as the real-world data it encounters diverges from the data it was trained on (e.g., due to changes in patient demographics or clinical practices).
NIST AI RMF	The National Institute of Standards and Technology's AI Risk Management Framework, a voluntary framework for identifying and managing AI risks across the lifecycle, built on four functions: Govern, Map, Measure, Manage.
ONC (Office of the National Coordinator for Health IT)	The U.S. federal entity responsible for health IT policy and programs, including regulations on AI transparency in certified health IT systems.
PCCP (Predetermined Change Control Plan)	An FDA framework that allows AI/ML device manufacturers to pre-specify planned modifications to their algorithms, enabling continuous learning without requiring a new submission for each update.
PMA (Premarket Approval)	The most rigorous FDA pathway for high-risk medical devices, requiring valid scientific evidence (typically clinical trials) to demonstrate safety and effectiveness.
Prospective Study	

Term	Definition
	A research study that follows participants forward in time, collecting data as events occur. Generally considered stronger evidence than retrospective studies.
RCT (Randomized Controlled Trial)	The gold standard of clinical evidence, in which participants are randomly assigned to an intervention or control group to measure the effect of a treatment or intervention. Only 5-12% of AI healthcare tools have RCT validation.
RCM (Revenue Cycle Management)	The financial process that healthcare organizations use to track patient care episodes from registration and appointment scheduling to the final payment of a balance.
Retrospective Study	A research study that looks backward at existing data. Generally considered weaker evidence than prospective studies due to potential for selection bias and confounding.
SaMD (Software as a Medical Device)	Software intended to be used for one or more medical purposes without being part of a hardware medical device. Most AI healthcare tools are classified as SaMD.
TRL (Technology Readiness Level)	A scale (1-9) used to assess the maturity of a technology. TRL 1-4 = research/development; TRL 5-7 = validation/demonstration; TRL 8-9 = clinical integration/deployment.
TRIPOD+AI	An extension of the TRIPOD reporting guideline for prediction models that includes specific items for AI-based prediction models, ensuring transparent and complete reporting.

18. AI & HEALTHCARE GOVERNANCE RESOURCES

The following resources represent the most authoritative and current guidance available for healthcare leaders navigating the governance of AI in medicine. They are organized by organization and cover the full spectrum from global ethical frameworks to U.S. regulatory specifics to practical implementation toolkits.

Table: Quick Reference — Top AI & Healthcare Governance Resources

Resource	Focus	Best For
AMA	Physician-facing governance toolkit, policy, CPT codes	Health systems, practicing physicians
CHAI	Multi-stakeholder AI best practices	Organizations building/deploying health AI

Resource	Focus	Best For
NAM	AI Code of Conduct, patient safety	Institutional leaders, policymakers
WHO	Global ethics & governance guidance	International perspective, LMICs
FDA	Medical device AI regulation	Device developers, clinical AI companies
NIST	AI Risk Management Framework	All organizations (baseline framework)
ONC	Health IT transparency rules	EHR vendors, health IT developers
URAC	AI accreditation standards	Organizations seeking certification
HSCC	AI cybersecurity governance	CISOs, security teams
HealthAI	Curated global AI governance resources	Researchers, policy analysts
CTA	Industry standards and convening	Tech companies, health systems
Alliance for Health Policy	Policy dialogue and analysis	Policymakers, advocates

1. American Medical Association (AMA) — Augmented Intelligence in Medicine

Website: ama-assn.org/practice-management/digital-health/augmented-intelligence-medicine

The AMA is arguably the single most important physician-facing resource for AI governance. Key offerings include the **STEPS Forward® "Governance for Augmented Intelligence" Toolkit** — an 8-step guide for health systems to establish AI governance frameworks — as well as AI Advocacy Principles covering oversight, transparency, generative AI policies, physician liability, and data privacy. The AMA's **Center for Digital Health and AI**, launched October 2025, places physicians at the center of shaping AI tools. Physician AI usage jumped from 38% in 2023 to 66% in 2024.

2. Coalition for Health AI (CHAI)

Website: chai.org

With nearly 3,000 member organizations, CHAI is the leading multi-stakeholder coalition driving responsible AI adoption in health. It convenes health systems, regulators, payers, clinicians, and industry leaders to shape and evaluate AI best practices. Their consensus-driven approach makes them a gold-standard resource for organizations building or deploying health AI.

3. National Academy of Medicine (NAM) — AI Code of Conduct

Website: nam.edu

NAM released a landmark *AI Code of Conduct for Health and Medicine* (May 2025) presenting six commitments and 10 principles: **Advance Humanity, Ensure Equity, Engage Impacted Individuals, Improve Workforce Well-Being, Monitor Performance, and Innovate and Learn**. NAM also launched a major "Patient Safety in the Era of AI" initiative (beginning spring 2026) co-chaired by leaders from Mayo Clinic and CommonSpirit Health.

4. World Health Organization (WHO) — AI for Health

Website: who.int/initiatives/global-initiative-on-ai-for-health

WHO provides the primary global governance framework through its *Ethics and Governance of AI for Health* (2021) — the first global guidance document — as well as updated guidance on Large Multi-Modal Models (LMMs) for health and the **Global Initiative on AI for Health (GI-AI4H)**, a joint effort with ITU and WIPO providing benchmarking, standards, and strategic guidance.

5. U.S. Food and Drug Administration (FDA) — AI/ML in Medical Devices

Website: fda.gov/medical-devices/software-medical-device-samd

The FDA is the key U.S. regulator for AI-enabled medical devices. Critical resources include the **AI/ML SaMD Action Plan** covering Good Machine Learning Practices (GMLP) and Predetermined Change Control Plans (PCCP), the **AI-Enabled Medical Devices List** (updated mid-2025), and the **Digital Health Center of Excellence (DHCoE)**.

6. NIST AI Risk Management Framework (AI RMF)

Website: nist.gov/itl/ai-risk-management-framework

The NIST AI RMF (released January 2023) has become the de facto baseline framework for healthcare AI governance. It is built on four core functions — **Govern, Map, Measure, Manage** — and provides voluntary, structured guidance for identifying and managing AI risks across the lifecycle. Healthcare organizations increasingly reference it for internal governance programs, and it aligns with HIPAA, FDA, and ONC requirements.

7. ONC — Office of the National Coordinator for Health IT

Website: healthit.gov

ONC's **HTI-1 Final Rule** (December 2023) established critical transparency requirements for AI/ML algorithms in certified health IT, including a formal definition of **Predictive Decision Support Interventions (Predictive DSI)**, mandated disclosure of algorithm development processes and data sources, and requirements for **Intervention Risk Management** for each Predictive DSI.

8. URAC — Health Care AI Accreditation

Website: [urac.org](https://www.urac.org)

URAC offers a **Health Care AI Accreditation** — a standards-based framework developed with input from healthcare, technology, and patient safety experts. It helps organizations demonstrate responsible governance and meaningful human oversight, providing confidence as innovation outpaces regulation.

9. Health Sector Coordinating Council (HSCC) — AI Cybersecurity Guidance

HSCC's Cybersecurity Working Group is releasing phased 2026 guidance on AI cybersecurity risks in healthcare, including an **AI Governance Maturity Model** for assessing capabilities, a **five-level autonomy scale** to classify AI tools and align human oversight with risk, and guidance on third-party AI vendor vetting and supply chain monitoring.

10. HealthAI — Knowledge Hub on AI Governance

Website: healthai.agency/knowledge-hub

HealthAI maintains a curated repository of global reports, publications, and policy documents on AI governance in health, including resources from WHO, the UN, OECD, and regional bodies. It is an excellent one-stop aggregator for staying current on international governance developments.

11. Consumer Technology Association (CTA) — Health AI Collaborative

Website: cta.tech

CTA convenes major healthcare associations, tech companies, and regulators through its **Health AI Collaborative** and **Health AI Planning Council**. Notable members include HCA Healthcare, Microsoft, Google, Amazon Web Services, and AdvaMed. CTA developed the first ANSI-accredited standard for health AI.

12. Alliance for Health Policy

Website: allhealthpolicy.org

A nonpartisan, nonprofit organization whose 2025–2026 Signature Series focuses specifically on **AI's transformative power in healthcare and health policy**, convening cross-sector dialogue with experts in both policy and practice.

2026 DrGPT AI Healthcare Index | First Edition, February 2026 | Harvey Castro MD MBA | www.HarveyCastroMD.com

Share This Report & Join the Movement

If this report helped you cut through the AI healthcare hype, share it with a colleague who needs it.

Post on LinkedIn or X with #DrGPTIndex

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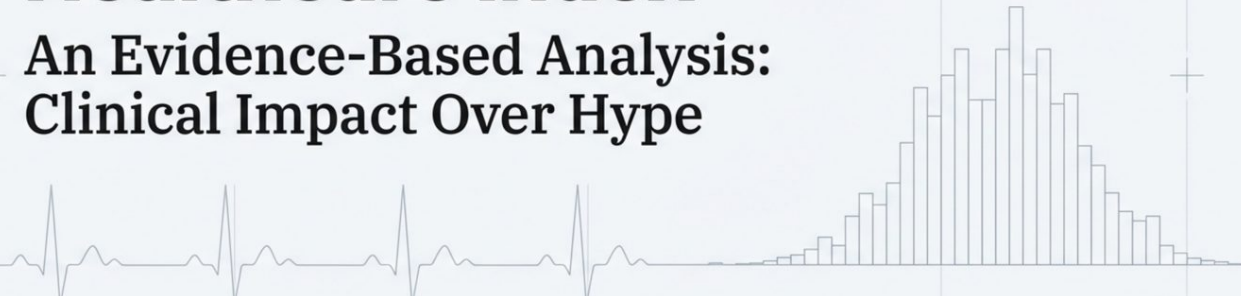
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Appendix: Visual Summary

The following 19 slides provide a visual overview of the 2026 DrGPT AI Healthcare Index. These slides are designed to be shared independently on LinkedIn, X, and in presentations. Use them to communicate the key findings of this report to your team, board, or colleagues.

2026 DrGPT AI Healthcare Index

An Evidence-Based Analysis: Clinical Impact Over Hype



Authored by:
Harvey Castro, MD, MBA
Chief AI Officer, Phantom Space Corp.


Date: February 21, 2026

Slide 1 of 19 — 2026 DrGPT AI Healthcare Index Visual Summary

Executive Dashboard: The State of AI Healthcare 2026

Market Size (2035)
\$543B 
 Projected Growth

2025 Funding
\$14.2B 
 +35% YoY (Digital Health)

The Evidence Gap
74% 
 of tools lack clinical validation

Safety Alert
182 
 Medical Device Recalls

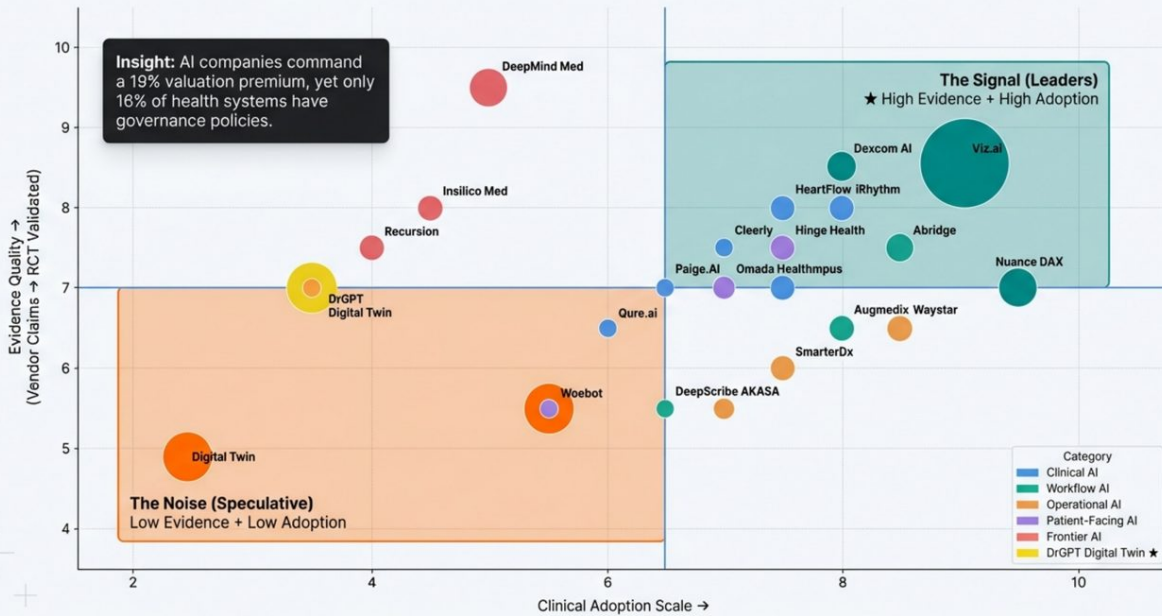
Navigation Guide

-  **CMOs/CIOs** → Jump to Leaders & Procurement
-  **Investors** → Jump to Market Trends
-  **Regulators** → Jump to Governance Matrix

Slide 2 of 19 — 2026 DrGPT AI Healthcare Index Visual Summary

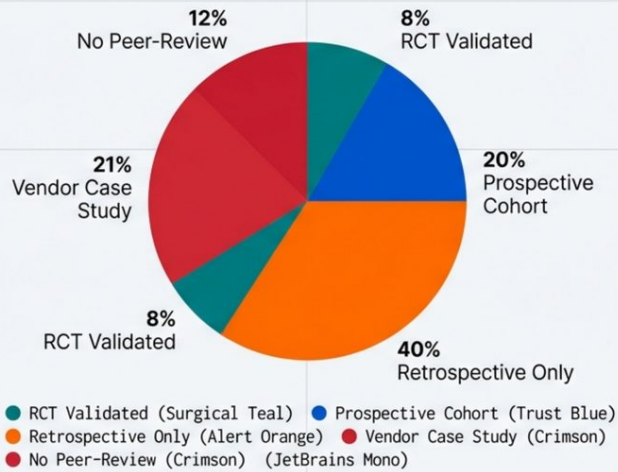
Bedside Impact vs. Boardroom Presentations

Adoption Scale does not always correlate with Evidence Quality.



Slide 3 of 19 — 2026 DrGPT AI Healthcare Index Visual Summary

The Evidence Crisis: Where Validation Actually Stands







Hard Truths:

- ⚠️ Only 5-12% of tools meet the RCT Gold Standard.
- ⚠️ 91% of FDA clearances use the 510(k) pathway (no human testing mandated).
- ⚠️ GenAI Diagnostic Accuracy: 52.1% (No advantage over physicians).

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The 'Theranos' Red Flag Checklist

Criteria for scrutinizing vendor claims

 <p>No Peer-Reviewed Publications</p> <p>Common in early startups. Science by press release.</p>	 <p>Claims > Evidence</p> <p>e.g., "Autonomous Diagnosis" asserted without FDA clearance.</p>	 <p>Hidden Algorithms</p> <p>Undisclosed validation data or "Black Box" IP defenses.</p>	 <p>Direct-to-Consumer Marketing</p> <p>Bypassing clinicians to sell directly to patients without trials.</p>
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Current Status: Overhype indicators present in 30-40% of evaluated companies.

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Regulatory Landscape & The Governance Gap

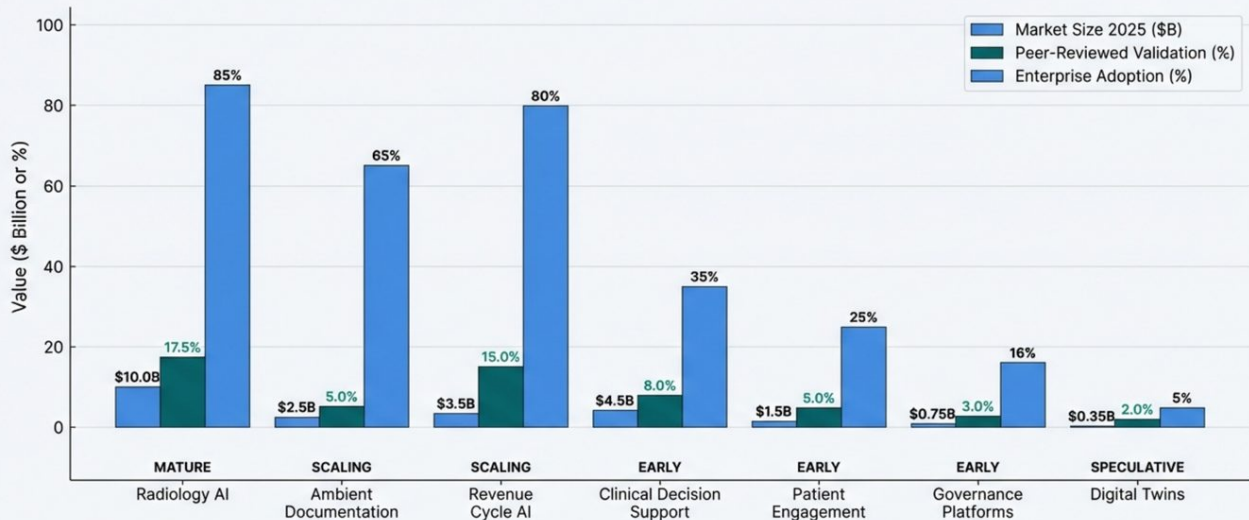
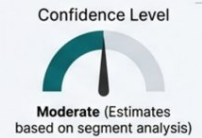


Critical Gap

- **Enforcement Gap:** Average time to recall for high-risk devices is < 2 years.
- **Monitoring Gap:** Lack of PCCP enforcement for model drift.

Slide 6 of 19 — 2026 DrGPT AI Healthcare Index Visual Summary

Market Maturity Map: Size vs. Clinical Adoption



Source: 2026 DrGPT AI Healthcare Index | Harvey Castro MD MBA | www.harveycastromd.com

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Clinical AI: Radiology, Cardiology, Oncology

Status: Mature but Fragmented | Confidence: High

**Warning:
Risk Watch:**
Beware 'Autonomous
Diagnosis' claims
lacking FDA
clearance.

Leaderboard			
	Company	Specialty	Highlights
1	Aidoc	Radiology	30+ Algorithms, aiOS platform
2	Viz.ai	Neuro/Vascular	Stroke time reduction, 1,400+ hospitals
3	HeartLung	Cardio	10 modules, opportunistic screening

**Evidence Spotlight:
Clearly**
CERTAIN Trial Result:
Management changes
in **57% of patients.**

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Physician Workflow: Ambient & Documentation

Status: Scaling Rapidly | Confidence: Moderate

**Reality Check:
Hallucination Risk**
Accuracy is rarely
100%. 'Zero-error'
marketing is a red
flag.

Leaderboard			
	Company	Providers / Systems	Highlights
1	Nuance DAX (Microsoft)	250k+ Providers	Deep Epic Integration
2	Abridge	Health Systems	Peer-reviewed efficiency studies
3	Augmedix	Acute/Ambulatory	Hybrid human-AI model

**ROI:
1-2 Hours**
Time saved per day
on documentation.



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Operational & Revenue Cycle AI

Status: **High ROI** / **Low Clinical Risk** | Confidence: **High**

Leaderboard

	Company	Area	Highlights
1	Waystar	RCM	Deep integration, hard ROI data
2	SmarterDx	CDI	Clinical Documentation Improvement
3	AKASA	Automation	RCM Automation

1
99.8%
Clean Claim Rate



Validated Metric

2
+\$440k
Annual Revenue per Practice




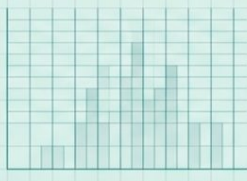


Financial Impact

Risk Factor: The "Arms Race" — AI Denials (Payers) vs. AI Appeals (Providers).

Slide 10 of 19 — 2026 DrGPT AI Healthcare Index Visual Summary

Patient-Facing AI: The 'Wild West'

JetBrains Mono | Status: **Early / Mixed Evidence** | Confidence: **Low to Moderate**

THE SIGNAL (Validated)	THE NOISE (Risky)
<p>Dexcom / Hinge Health</p>  <p>Attributes:</p> <ul style="list-style-type: none">● RCT Validated● Payer-driven,● FDA Cleared 	<p>Generic Wellness Chatbots</p>  <p>Attributes:</p> <ul style="list-style-type: none">● Low evidence,● 'Wellness Exemption' loopholes,● Unregulated. 

! Critical Risk: Silent Triage Failures. AI failing to escalate suicidality or heart attacks.

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Infrastructure & Data Centers: The Engine Room

Optimization

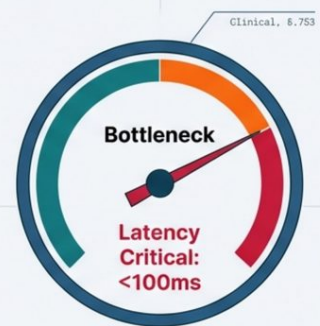
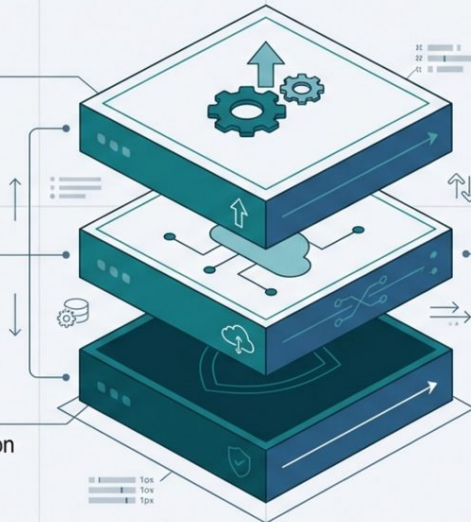
Phantom Space - GPU cost optimization.

Cloud & Edge

Microsoft / Azure - Strict BAA dependencies.

Hardware & Compute

NVIDIA (Clara) - The validation bedrock (MONAI)



Required response time for ICU/Surgery. Cloud latency risks edge failure.

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Frontier AI: Pharma R&D & Digital Twins

Status: Speculative to Research-Grade

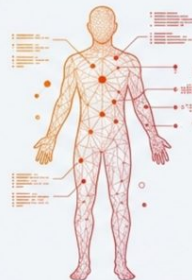
Pharma R&D (High Evidence)



DeepMind (AlphaFold)
[Validated: Protein Structure Prediction]

Insilico Medicine
[Clinical Trials: Generative Biology]

Digital Twins (Emerging)



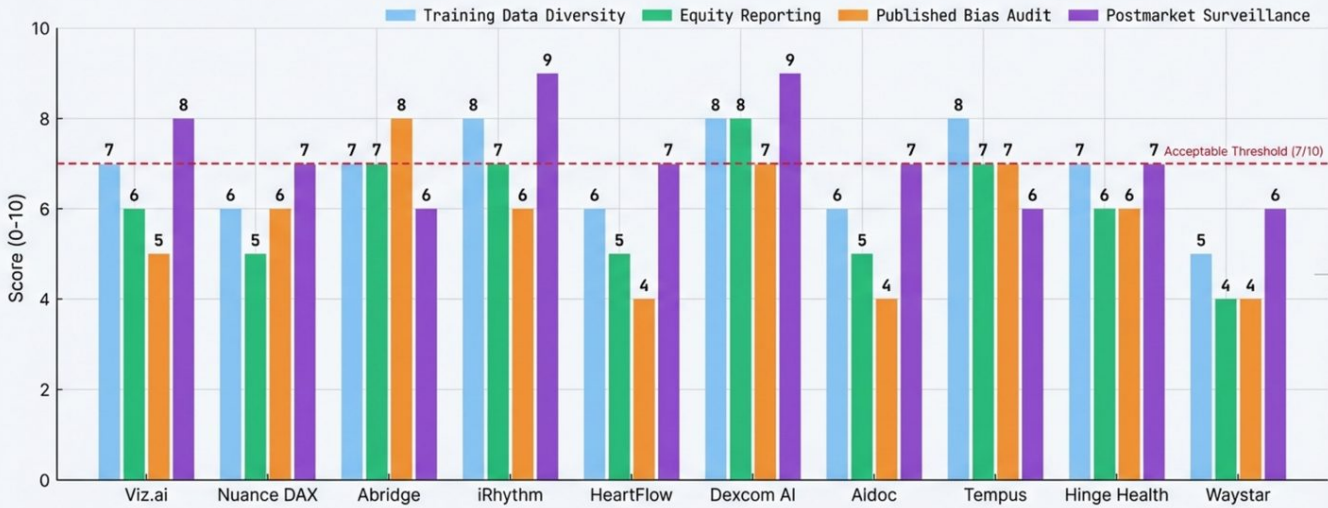
DrGPT (Clinician-designed, UAE Partnership)
[Research: Clinical Simulation]

Status: Early / Hype-Driven

Reality Check: 'Digital Twins' are currently research-stage. Bedside application is minimal. Risk of synthetic data poisoning.

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Bias & Equity Scuity Scorecard: The Top 10 Leaders

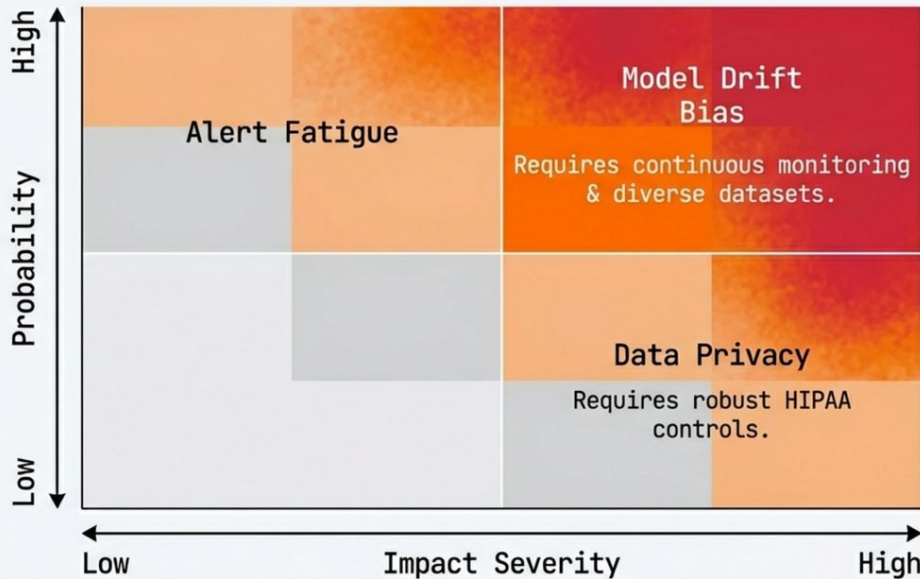



Top Performers

- Viz.ai (Score 86) - Acute triage
- Abridge (Score 84) - Documentation
- Tempus (Score 84) - Precision oncology

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The Governance Risk Matrix



 **Emerging Risk: Clinical Overreliance (The 'AI as Attending' fallacy).**

Over-trust in AI recommendations without independent clinical judgment.

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Procurement & Implementation Checklist

Non-Negotiable Questions for Vendors

EVIDENCE ✓

Question: Show me the peer-reviewed, prospective validation.

Note: Vendor case studies are insufficient.

Vendor Data

Internal Studies

→

✗

Peer-Reviewed, Prospective Studies

→

VALIDATED

Safe/Validated
Hype/Risk

LIFECYCLE ✓

Question: Show me your PCCP (Predetermined Change Control Plan).

Note: Essential for managing model drift.

Safe/Validated
Hype/Risk

SECURITY ✓

Question: Show me the SOC 2 report and Business Associate Agreement (BAA).

Note: Non-negotiable for HIPAA compliance.

SECURE DATA ENVIRONMENT

SOC 2 Report

BAA

NON-COMPLIANT ACCESS

HIPAA COMPLIANT ACCESS

Safe/Validated
Hype/Risk

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The Model Dossier: A Standard for Transparency

AI Model Dossier

1. Intended Use

- Target population, setting
- Specific clinical task
- Excluded populations

2. Training Data

- Size (e.g., 1M+ samples)
- Diversity sources (Institutions, Demographics)
- Data provenance & annotation process

3. Performance Metrics

- Sensitivity, specificity, AUC-ROC
- Known gaps in subgroups
- Validation study details (peer-reviewed)

4. Bias & Fairness

- Audit results (Demographic parity)
- Mitigation strategies applied
- Remaining disparities noted

5. Known Limitations

- Failure modes & conditions
- Edge cases with high error
- Contraindications & risks

+

Demand this document from every vendor before purchase.

Standardizes transparency across all AI procurements, enabling informed clinical and operational decision-making. Non-negotiable for high-impact tools.

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Strategic Call to Action

“Treat AI as a high-quality resident, not the attending. Bedside impact is non-negotiable.” — Dr. Harvey Castro

FOR BOARDS.

JetBrains Mono

- ✓ Demand independent prospective data on outcomes.

FOR CLINICIANS.

JetBrains Mono

- ✓ Lead design and hold veto power in governance.

FOR REGULATORS.

JetBrains Mono

- ✓ Clarify liability for AI decisions.

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Methodology & U.S. . .

Scoring Breakdown:

Clinical Impact (25%)
Evidence Strength (20%)
Safety (15%)
Workflow (15%)
Economic (10%)
Scalability (10%)
Transparency (5%)

Disclosure: Dr. Castro is Chief AI Officer at Phantom Space Corp.

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