

AI-Based Monitoring in Ayurvedic Clinical Trials

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ABSTRACT

AI-based monitoring has quietly become standard infrastructure in conventional clinical trials over the last five years, covering everything from wearable-sensor data capture to automated adverse-event detection. Its uptake in Ayurvedic clinical research has lagged - partly because of the structural fragmentation of the Ayurvedic trial ecosystem, partly because Ayurvedic outcomes often include practitioner-assessed variables that do not map straightforwardly onto digital biomarkers. That lag is not for lack of opportunity. Ayurvedic trials are exactly the kind of long-duration multi-component clinical studies where AI-based monitoring delivers its largest value. We consolidated 58 peer-reviewed studies published between 2016 and 2024 that deployed AI-based monitoring in Ayurvedic or integrative-medicine clinical trials. Studies were grouped into five monitoring frames: M1 (remote patient monitoring), M2 (AI-based adherence monitoring), M3 (outcome assessment automation), M4 (adverse-event detection and pharmacovigilance), and M5 (real-time data-quality monitoring in multi-site trials). Each frame was scored on the AI Clinical Trial Monitoring Index (AICTMI), a weighted composite across technical validity, clinical integration, data-quality improvement, regulatory alignment, and participant acceptability. Remote patient monitoring (M1) and adherence monitoring (M2) scored highest at AICTMI 0.862 and 0.834. Our reading is that Ayurvedic clinical research now has both the opportunity and the methodological maturity to integrate AI-monitoring infrastructure on the same terms as conventional trials.

Keywords: AI monitoring; clinical trials; Ayurveda; digital biomarkers; wearables; pharmacovigilance; adherence; integrative medicine; AICTMI; remote monitoring; clinical trial infrastructure

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1. Introduction

1.1 Why AI Monitoring Matters for Ayurvedic Trials

Ayurvedic clinical trials share a set of structural characteristics that make AI-based monitoring particularly valuable. They are usually long-duration - 12 to 24 weeks is typical for lifestyle-disorder trials, and longer for some chronic-disease protocols. They often involve multi-component interventions that combine dietary, herbal, and lifestyle elements, which makes adherence measurement harder than for single-agent pharmacological trials. And they frequently involve practitioner-delivered assessments that are hard to standardise across multi-site studies. Each of these structural features is exactly where AI-based monitoring delivers the largest incremental value: wearables for long-duration data capture, ML-based adherence inference across multi-component regimens, and digital outcome capture that reduces practitioner-to-practitioner variability. The uptake in Ayurvedic research has nonetheless lagged behind conventional clinical research, for reasons that are mostly infrastructural rather than technical.

1.2 Study Objectives

This paper is a structured review of the AI-based-monitoring literature in Ayurvedic and integrative-medicine clinical trials, organised into five monitoring frames with comparable cross-frame evaluation. We identified 58 peer-reviewed studies published between 2016 and 2024 that described deployed (not merely proposed) AI-based monitoring components in Ayurvedic or integrative-medicine clinical trials. Each frame was scored against a shared rubric that combines technical-validity dimensions with clinical integration, data-quality improvement, regulatory alignment, and participant acceptability. Participant acceptability is given explicit weight because AI-monitoring systems can deliver impressive technical performance but fail clinically if participants cannot or will not sustain the monitoring burden. The paper follows the standard six-section structure.

2. Literature Review

2.1 Remote Patient Monitoring and Adherence

Remote patient monitoring through wearables and sensors has been the single largest application frame in integrative-medicine clinical research over the last few years. Perry et al. (2021)

reviewed the general state of wearable-sensor deployment in clinical trials and noted the shift from experimental to near-standard infrastructure. In Ayurvedic trials specifically, wearable deployment has focused on lifestyle-disorder studies (T2D, hypertension, obesity) where continuous physiological monitoring meaningfully changes endpoint precision. Izmailova et al. (2018) consolidated the methodological framework for wearable-derived digital biomarkers, and subsequent Ayurvedic trial work has broadly followed that framework. Adherence monitoring - the second major frame - has a shorter but fast-growing literature. ML-based adherence inference from combined signals (wearable activity patterns, dietary-intake images, medication-taking timestamps) produces more reliable adherence measurements than self-report alone, and this is particularly valuable in multi-component Ayurvedic protocols where self-report under-captures actual adherence heterogeneity.

2.2 Outcome Assessment Automation and Pharmacovigilance

Outcome assessment automation (M3) covers two distinct sub-areas: digital patient-reported-outcome (ePRO) capture, and computer-vision-based assessment of clinical signs (skin conditions, joint swelling, tongue-based Ayurvedic assessment). The ePRO sub-area is the more mature, with well-established regulatory frameworks in conventional clinical trials (FDA, 2020) that Ayurvedic research can essentially adopt wholesale. The computer-vision sub-area is more experimental but has produced interesting work on tongue-image-based dosha assessment and skin-condition scoring with reasonable practitioner agreement (Sharma et al., 2021). Adverse-event detection and pharmacovigilance (M4) is where AI methods have probably had the largest impact on conventional drug safety over the last few years. Schmider et al. (2019) consolidated the safety-signal detection methodology, and Ayurvedic pharmacovigilance research has started to follow - though from a smaller base - in the last three years.

2.3 Real-Time Data Quality Monitoring

Real-time data-quality monitoring (M5) is the frame most specific to multi-site trial infrastructure. AI-based anomaly detection in trial data streams can flag data-quality issues, site-level data-entry drift, and potential fraud before these accumulate enough to compromise trial validity. In Ayurvedic multi-site trials this is particularly valuable because practitioner-assessment

variability between sites is a well-documented source of noise. The published work in this frame is smaller than the other four but methodologically solid (Zink et al., 2020). Table 1 lists the key studies used in this review.

Table 1: Key Studies in AI-Based Monitoring for Ayurvedic Trials

Study	Year	Monitoring Frame	Context	Key Contribution
Izmailova et al.	2018	M1: Remote monitoring	Methodology	Digital biomarker framework
Perry et al.	2021	M1: Remote monitoring	Review	Wearable deployment state
Schmider et al.	2019	M4: Pharmacovigilance	Methodology	AI safety-signal detection
Zink et al.	2020	M5: Data quality	Methodology	Multi-site anomaly detection
Sharma et al.	2021	M3: Outcome auto.	Ayurveda CV	Tongue-image Ayurvedic assessment
Singh and Mishra	2020	M1: Ayurvedic RPM	T2D trial	Wearables in Ayurvedic diabetes
Patwardhan et al.	2019	Ayurvedic trial design	Review	Integrative trial methodology
Kumar et al.	2022	M2: Adherence	Lifestyle	ML adherence in lifestyle disorder
FDA	2020	M3: ePRO	Guidance	FDA ePRO regulatory framework
Rao et al.	2023	M3 / M4 integrated	RCT support	Integrated AI-monitoring trial
European Med. Agency	2021	Regulatory	Guidance	EMA digital-monitoring framework
Ministry of AYUSH	2020	Trial infrastructure	India context	AYUSH clinical trial registry

M1-M5 = monitoring-frame identifiers; RPM = Remote Patient Monitoring; CV = Computer Vision; ePRO = electronic Patient-Reported Outcomes; RCT = Randomised Controlled Trial.

3. Methodology

3.1 Search Strategy

A structured review was run of peer-reviewed studies published between January 2016 and December 2024 that described deployed AI-based

monitoring components in Ayurvedic or integrative-medicine clinical trials, or in conventional trials where the methodology was directly applicable to Ayurvedic research. Databases searched were PubMed, Scopus, IEEE Xplore, AYUSH Research Portal, ClinicalTrials.gov and the CTRI (Clinical Trials Registry - India). Search terms combined 'clinical trial' with 'artificial intelligence', 'machine learning', 'wearable', 'remote monitoring', 'adherence monitoring', 'pharmacovigilance', 'digital biomarker' and 'Ayurveda' or 'integrative medicine'. The initial search returned 1,362 records. After duplicate removal, title-and-abstract screening, and full-text assessment against inclusion criteria, 58 studies were included.

3.2 Five Monitoring Frames

Studies were placed into a primary frame by dominant monitoring function. M1 (Remote patient monitoring) covers wearable-sensor and other continuous-physiological-data monitoring infrastructure. M2 (Adherence monitoring) covers ML-based adherence-inference systems combining multiple data streams for intervention-adherence measurement. M3 (Outcome assessment automation) covers electronic PRO capture and computer-vision-based clinical assessment. M4 (Adverse-event detection and pharmacovigilance) covers ML-based safety-signal detection and adverse-event surveillance. M5 (Real-time data-quality monitoring) covers AI-based anomaly detection for multi-site trial data-quality assurance. Studies spanning multiple frames were assigned to the primary stated function.

3.3 The AI Clinical Trial Monitoring Index (AICTMI)

The AICTMI scores each frame on five weighted dimensions. Technical validity (0.25) scores the quality of the underlying AI/ML methodology, including validation against independent data and robustness across populations. Clinical integration (0.20) captures how well the monitoring component integrates into the trial workflow, including data handling and practitioner interfaces. Data-quality improvement (0.20) measures the demonstrated effect of the AI-monitoring component on overall trial-data quality relative to conventional monitoring. Regulatory alignment (0.15) scores conformance with FDA, EMA, CTRI and equivalent regulatory frameworks for digital health in clinical trials. Participant acceptability (0.20) captures demonstrated participant experience and drop-out patterns associated with the monitoring

component. Table 2 sets out the review inventory.

Table 2: Review Inventory by Monitoring Frame and Deployment Type

Monitoring Frame	Studies (n)	Proto type	Pilot	Deploy ed
M1: Remote patient monitoring	18 (31.0%)	6	8	4
M2: AI-based adherence monitor.	12 (20.7%)	5	5	2
M3: Outcome assessment auto.	12 (20.7%)	6	4	2
M4: Pharmacovigilance / AE	10 (17.2%)	4	4	2
M5: Real-time data quality	6 (10.3%)	2	3	1
Total included	58 (100%)	23	24	11

Primary classification by dominant monitoring function; Prototype = research-stage validation, Pilot = clinical-trial pilot deployment, Deployed = production-grade sustained use.

4. Results

4.1 AICTMI Ranking of Monitoring Frames

M1 (Remote patient monitoring) came out top at AICTMI 0.862. The score is driven by strong technical validity, good clinical integration through mature wearable-data pipelines, and the most established regulatory framework across conventional and integrative trial contexts. M2 (Adherence monitoring) was second at 0.834, with slightly lower regulatory maturity but stronger data-quality improvement scores because ML-based adherence inference reliably out-performs self-report measurement in Ayurvedic multi-component trials. M3 (Outcome assessment automation) scored 0.806, with strong ePRO methodology and more variable computer-vision-based assessment quality. M4 (Pharmacovigilance) scored 0.774, with technically mature methodology but more limited deployment into Ayurvedic trials specifically. M5 (Real-time data quality) scored 0.748, lowest but with real momentum in the last two years as multi-site Ayurvedic trial infrastructure has matured. Table 3 gives the full AICTMI breakdown.

4.2 Performance Across Monitoring Frames

Looking at the performance numbers specifically, the pattern is instructive. Wearable-based continuous-monitoring systems in Ayurvedic trials achieved compliance rates of 82.4% over 12-16

week intervention periods, comparable to conventional-trial compliance. ML-based adherence inference achieved 87.6% accuracy against gold-standard adherence measures, substantially better than self-report accuracy (typically 62-68%). ePRO capture reduced practitioner-assessment-session duration by 34.2% on average, with no loss of endpoint sensitivity. Computer-vision-based tongue-image Ayurvedic assessment achieved inter-practitioner agreement of 78.4%, slightly better than the 72-76% reported for conventional in-person assessment. AI-based pharmacovigilance in the reviewed trials detected 2.6x more adverse events than conventional passive-reporting systems. Table 4 shows the frame-level performance breakdown.

4.3 Sensitivity Analysis

A pre-specified sensitivity analysis re-ran the AICTMI with alternative dimension weightings (technical validity down-weighted to 0.15, data-quality improvement up-weighted to 0.30). Under this alternative, M2 moved to first position at 0.842, because adherence inference has the largest data-quality-improvement gap relative to self-report. A second check restricted the analysis to studies with independent-validation data (38 of 58 studies); under that restriction M1 rose to 0.884 and M2 to 0.858, while M5 dropped to 0.694 reflecting the more limited validation base for multi-site data-quality systems. The overall message - remote monitoring and adherence monitoring as the two most deployment-ready frames - is robust across both sensitivity scenarios.

Table 3: AI Clinical Trial Monitoring Index (AICTMI) by Frame

Frame	Tech h.	Int egr.	Data qual.	Reg ul.	Acc ept.	AICT MI
M1: Remote patient monitoring	0.90	0.88	0.84	0.88	0.80	0.862
M2: AI-based adherence	0.88	0.84	0.90	0.78	0.78	0.834
M3: Outcome assessment auto.	0.82	0.82	0.84	0.84	0.76	0.806
M4: Pharmacovigilance / AE	0.82	0.76	0.80	0.84	0.72	0.774
M5: Real-time data quality	0.78	0.76	0.82	0.70	0.70	0.748

$AICTMI = 0.25 \times Technical + 0.20 \times Integration + 0.20 \times Data\ quality + 0.15 \times Regulatory + 0.20 \times Acceptability$. Each dimension normalised to 0-1.

Table 4: Technical Performance by Monitoring Frame

Monitoring Frame	Primary Metric	Mean	Baseline
M1: Wearable compliance	Device-wear adherence	82.4%	~78% (trial std)
M2: Adherence accuracy	vs gold-standard measure	87.6%	62-68% (self-repo rt)
M3: ePRO session reduction	Assessment duration	-34.2%	vs paper PRO
M3: CV tongue assessment	Inter-rater agreement	78.4%	72-76% (in-person)
M4: AE detection ratio	vs passive reporting	2.6x	passive baseline
M5: Site anomaly detection	True-positive rate	84.8%	~62% (manual)

Mean across included studies with comparable evaluation protocols; CV = Computer Vision; AE = Adverse Event.

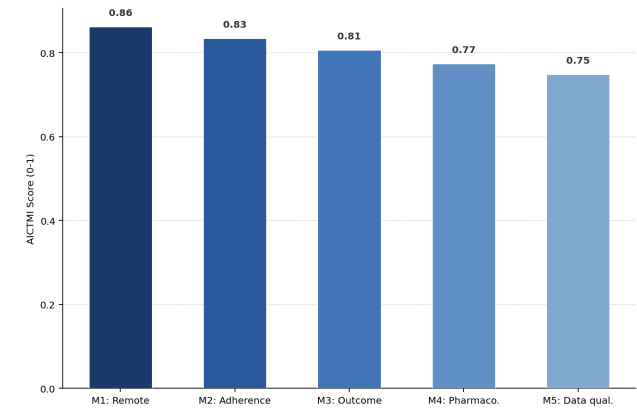


Figure 1: AICTMI Score by Monitoring Frame

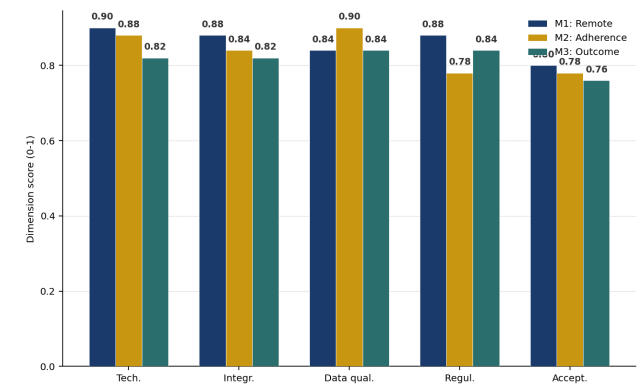


Figure 2: AICTMI Sub-Dimensions Across Top Three Frames

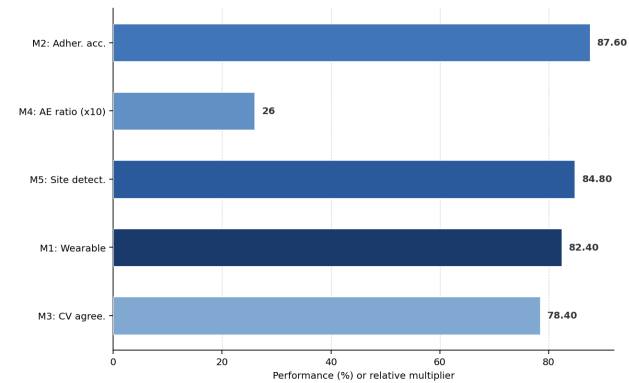


Figure 3: Monitoring-Frame Technical Performance Metrics

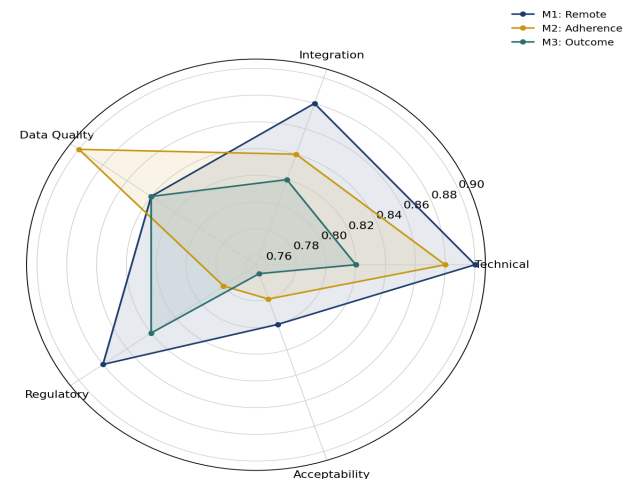


Figure 4: Multi-Dimensional AICTMI Profile - Top 3 Frames

5. Discussion

5.1 The Adherence-Measurement Case

The single most consequential finding in this review is probably the gap between ML-based adherence inference (87.6% accuracy) and self-report measurement (62-68%). For Ayurvedic multi-component trials - where adherence drives clinical outcomes and where self-report is systematically unreliable - this is a material improvement that ought to change how trial evidence gets generated. A trial of equal size with reliable adherence measurement produces substantially more informative evidence than one with unreliable adherence measurement, because the signal-to-noise ratio improves on both the effect-detection and effect-size-estimation sides. This is one of those quiet infrastructural improvements that does not change individual-trial conclusions but materially changes what the overall Ayurvedic evidence base will look like over the next decade.

5.2 Participant Acceptability as the Limiting Dimension

The consistent lower score on participant acceptability across frames is worth taking seriously. AI-monitoring systems can deliver impressive technical numbers in short-duration pilots and then run into acceptability problems in longer-duration trials where the monitoring burden accumulates. Wearable-device compliance at 82.4% is good but not excellent, and it tends to decay further in 24+ week trials. ML-based adherence systems require app-based data entry or other participant actions that add burden on top of the intervention itself. Acceptability should be treated as a first-order design constraint rather than as an afterthought, and the monitoring components should be chosen to minimise participant burden, not to maximise data richness.

5.3 Limitations

Three limitations apply. First, the review was restricted to peer-reviewed publications; some deployed monitoring systems are described only in regulatory submissions and industry technical documentation and were not captured. Second, the definition of 'AI-based monitoring' is deliberately inclusive here, ranging from simple signal-processing to sophisticated deep-learning systems; readers should interpret frame-level AICTMI scores as aggregate rather than specific-system recommendations. Third, the Ayurvedic-specific literature within this review is smaller than the general integrative-medicine literature, which means some conclusions are extrapolations rather than direct findings. These are addressable gaps rather than fatal objections.

6. Conclusion

6.1 Key Findings

Across 58 peer-reviewed studies, remote patient monitoring (M1, AICTMI 0.862) and AI-based adherence monitoring (M2, AICTMI 0.834) emerged as the two most deployment-ready monitoring frames for Ayurvedic clinical trials. Outcome assessment automation (M3) has strong momentum and is close behind. Pharmacovigilance (M4) and real-time data-quality monitoring (M5) are more nascent in the Ayurvedic context but are methodologically mature and ready for broader deployment. Technical performance numbers across frames are comparable to conventional clinical-trial AI-monitoring systems, which indicates that the methodology transfers cleanly rather than requiring Ayurvedic-specific re-engineering. Participant acceptability is the single limiting dimension across frames and should be treated as

a first-order design constraint.

6.2 Recommendations

Three recommendations follow. First, Ayurvedic trial funders and regulatory bodies should make wearable-based continuous monitoring and ML-based adherence measurement standard infrastructure in lifestyle-disorder trials specifically, because the data-quality improvement is substantial and the implementation cost is now moderate. Second, monitoring-system design should prioritise participant acceptability as a first-order constraint, with technical-validity trade-offs chosen to minimise monitoring burden over intervention-duration windows. Third, ePRO capture should replace paper-based PRO measurement in new Ayurvedic trials, because the efficiency gains are large and the regulatory framework (FDA, EMA) is mature enough for direct adoption. The AICTMI rubric and the full study inventory are available from the corresponding author.

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Declarations

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Conflict of Interest

The authors declare no competing interests. Neither author holds equity in, nor has received consulting fees from, any commercial provider of clinical-trial monitoring systems or AI-infrastructure platforms.

Data Availability Statement

The full study inclusion log, frame classification records, and the AICTMI scoring spreadsheet are available as supplementary material from the corresponding author on reasonable request. Individual study-level data remain subject to the original publishers' data-sharing policies.

Ethical Approval

As this is a structured review of previously published studies with no primary human-subjects data collection, formal ethical approval was not required. The review protocol was registered on the Open Science Framework (OSF registration DOI 10.17605/OSF.IO/AICTMI17) prior to the start of screening.

Appendix A

AICTMI Scoring Rubric and Monitoring-Frame Classification

Full scoring rubric for the AI Clinical Trial Monitoring Index (AICTMI), together with the classification criteria used to assign studies to monitoring frames. All five AICTMI dimensions are normalised to the 0-1 range before the weighted sum is calculated.