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MedTech AI Quality Benchmark: Validation and PCCPs

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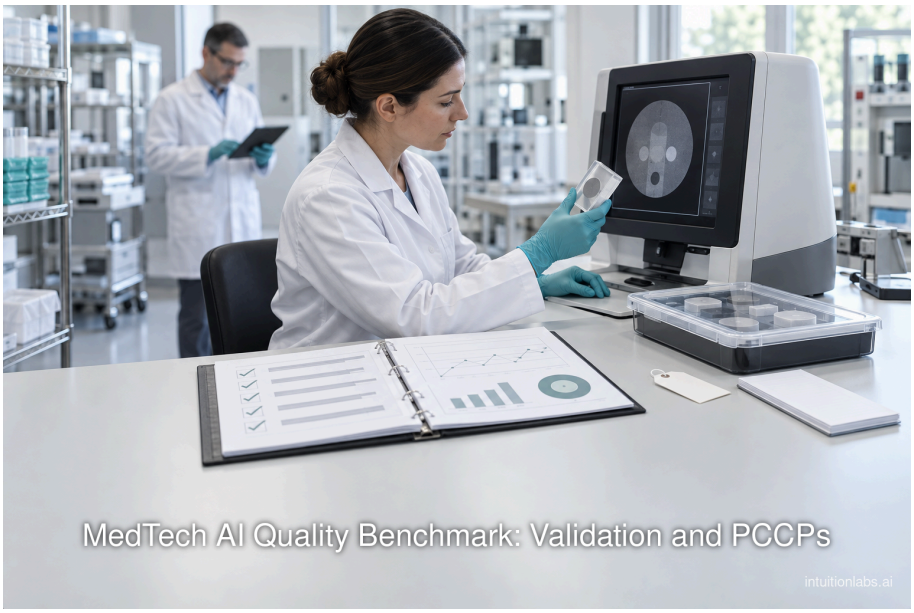

In this article

Executive Summary

The **2026 MedTech AI Quality Benchmark** is a measurement system for AI-enabled medical-device teams, not a claim that a convenience sample represents the market. It scores six capabilities: **clinical validation, data governance, predetermined change control plans (PCCPs), postmarket monitoring, complaint feedback, and model traceability**. Each capability receives 0 to 3 points, for an 18-point evidence-maturity total. Scores describe the evidence a team can produce, not device safety, regulatory status, or company quality. That distinction matters because the US Food and Drug Administration (FDA) says its AI-enabled-device list is not comprehensive (fda.gov). WHO emphasizes ethically sourced, representative health data (who.int), while IEC identifies validity periods as a data-quality concern (iec.ch). The public list is a useful appendix, not a denominator for the entire industry.

The core survey asks about observable practices. A clinical-evidence record distinguishes no product-level evaluation, retrospective evaluation, prospective evaluation, and post-deployment evaluation. External validation means applying an existing model without modification (nature.com), while the International Medical Device Regulators Forum (IMDRF) says its extent should be proportionate to risk (imdrf.org). The benchmark records site independence, prospective status, subgroup analysis, human-AI team evaluation, predeclared endpoints, missing answers, and the exact deployed version. It does not collapse those practices into a single yes or no item.

PCCP maturity is similarly evidence-based. FDA, Health Canada, and the UK regulator jointly identified five PCCP principles (gov.uk). Therefore, the survey separates **not planned, drafting, submitted, authorized but unused, and authorized with a change executed**. It also records model-change cadence, protocol version, approval record, and rollback evidence. This prevents planned activity from being reported as implemented capability.

The first edition should publish **raw n and item denominators before percentages**, suppress cells below a predeclared threshold, and disclose recruitment, uncovered populations, missingness, and weighting. AAPOR calls for the unweighted sample behind every subgroup estimate (aapor.org); STROBE calls for missing-data counts by variable (strobe-statement.org). Priority investment goes first to any capability at level 0, then to cross-system breaks such as a monitoring signal that cannot be traced to a complaint, model version, dataset, or approved change record.

Introduction and Background

AI-enabled medical-device teams face a practical evidence question before submission, acquisition diligence, or scale-up: **which lifecycle controls are demonstrable, and which exist mainly as intent?** Regulation describes expectations, but it does not provide a cross-company operating benchmark. IMDRF calls for deployed-model monitoring (imdrf.org), while current US quality-system rules require documented traceability procedures where applicable (ecfr.gov). Public device lists do not show whether teams run external-site testing, predefine drift thresholds, link complaints to model versions, or close investigations within a measured interval.

This report defines a repeatable annual benchmark for those practices. It is designed for product, software, clinical, quality, and regulatory leaders. The unit of analysis is a specific product or product program, not the respondent's employer. Respondents must identify their role and proximity to the evidence they report. The instrument separately records device class, regulatory pathway, modality, company stage, and whether the product is **authorized, submitted, in verification, or earlier-stage**. FDA itself distinguishes devices marketed through 510(k) clearance, a granted De Novo request, or an approved premarket approval application (PMA) (fda.gov). The report therefore uses "authorization" as the umbrella term and reserves "approval" for PMA where appropriate (fda.gov).

The benchmark measures process evidence, not company reputation. No vendor ranking is produced, no respondent is treated as representative of the whole market, and ownership is not used as a proxy for quality. The adjacent consultancy perspective is deliberately narrow: IntuitionLabs describes its own work as governed workflows measured before scaling (intuitionlabs.ai) and says its life-sciences scope includes medical devices and diagnostics (intuitionlabs.ai). That supports an evidence-first framing, but the firm is not a surveyed device product, a software-vendor comparator, or a row in any score table.

Benchmark Methodology and Limits

Sampling, respondents, and unit of analysis

The annual survey should use a documented nonprobability recruitment strategy across manufacturers, developers, clinical partners, and quality or regulatory professionals. AAPOR requires disclosure of whether a sample is probability-based or nonprobability-based (aapor.org) and identification of target-population segments not covered by the design (aapor.org). The Office for National Statistics provides another transparent precedent by explicitly excluding incomplete responses from analysis (ons.gov.uk). Those disclosures are more defensible than a broad "state of the industry" label.

Eligibility requires direct knowledge of one product program during the reporting year. The questionnaire records:

- **Respondent role:** product, software or machine learning, clinical, quality, regulatory, data, postmarket, or executive.
- **Evidence proximity:** owner, approver, contributor, informed stakeholder, or no direct access.
- **Product state:** authorized, under review, submission planned, verification or validation, prototype, or research only.
- **Regulatory context:** device class, current or intended pathway, jurisdictions, and product code where known.
- **Modality:** imaging, signal processing, digital pathology, monitoring, decision support, robotics, or other.
- **Change model:** locked model, periodically updated model, continuously learning research system, or unknown.
- **Company stage:** pre-revenue, first authorized product, scaling portfolio, or established portfolio.
- **One response rule:** one product program per response, with duplicates adjudicated using nonidentifying keys.

A recurring industry survey provides a useful format analogue, but not a substitute for method disclosure. Greenlight Guru calls its 2025 publication its sixth annual report and says it surveyed more than 500 professionals (greenlight.guru). The accessible landing page does not establish the recruitment frame, item denominators, or weighting for this benchmark, so those details must be published directly here.

Ethics, privacy, and disclosure control

Survey status should be determined before launch. NIH notes that some projects do not meet the Common Rule definition of research (nih.gov), but advises consulting an institutional review board (IRB) when the classification is uncertain (nih.gov). The protocol should document that determination, consent language, retention period, access controls, and whether contact data are separated from answers. HHS recommends addressing how online-study data are collected, transmitted, and stored (hhs.gov).

No universal small-cell threshold applies to this survey. One Office for National Statistics method suppresses outputs based on fewer than 10 people (ons.gov.uk), while a CDC cancer-data standard uses fewer than 16 cases (cdc.gov). These are contextual precedents, not transferable mandates. The benchmark should predeclare its own threshold after privacy review, apply complementary suppression when another cell could reveal the hidden value (census.gov), and never release respondent-level data.

Reproducibility package

Every edition should release the questionnaire, codebook, scoring script, aggregate tables, data-cleaning log, and a versioned public-data appendix. The package should state the field period, recruitment channels, invitation count where knowable, completed and partial responses, exclusions, item-level missingness, and exact denominator for each estimate. HHS also treats privacy and confidentiality provisions as part of limited review (hhs.gov). Percentages should use respondents who answered that item unless an alternate denominator is explicitly named. The Census Bureau provides a useful example by defining a published percentage denominator as establishments that answered the relevant question (census.gov).

Executive Maturity Scorecard

The scorecard asks whether evidence can be produced, linked, and reproduced. NIST describes an inventory as an organized database of system or model artifacts (nist.gov), and the UK National Cyber Security Centre connects configuration management to reproducibility (ncsc.gov.uk). The score does not award points for company size, funding, or an authorization outcome. **Level 0** means the evidence is absent or unknown. **Level 1** means a documented plan or isolated activity exists. **Level 2** means the control is implemented for the focal product. **Level 3** means it is implemented, measured, linked across systems, and periodically reviewed.

Table 1 summarizes the six-capability rubric. Each row is scored independently from 0 to 3, producing a maximum of **18 points**.

Capability	0: absent or unknown	1: planned or isolated	2: implemented	3: linked and measured
Clinical validation	No product-level clinical evaluation evidence	Protocol or retrospective internal study only	Completed evaluation on representative data, with version and endpoint records	External-site or prospective evidence as appropriate, subgroup results, human-AI workflow evaluation, and issue closure
Data governance	Dataset provenance or permitted use unknown	Inventory exists for selected datasets	Versioned provenance, inclusion rules, access, labeling and quality checks	Representativeness, validity period, shift checks, lineage and governance decisions are reviewed
PCCP and change control	No defined change boundaries	PCCP or change protocol in drafting	Approved internal protocol, or submitted or authorized PCCP status recorded accurately	Each executed change links specification, evidence, authorization basis, release and rollback
Postmarket monitoring	No named owner or metric	Owner or metric named without threshold	Production metrics, thresholds, cadence and escalation path active	Signals link to affected populations, model versions, investigations and corrective actions
Complaint feedback	Complaints cannot be linked to AI behavior	Manual case-by-case linkage	Standard categories and investigation record capture model relevance	Trend, complaint, monitoring, change and corrective-action records share traceable identifiers
Model traceability	Deployed version cannot be reconstructed	Repository tag or model identifier exists	Model, code, data, configuration, environment and approval are versioned	Deployment, prediction logs, monitoring, change decision and retirement record form an auditable chain

The total supports triage, not certification. A team scoring 12 can still have a critical level-0 gap, so the six row scores must always accompany the total. Maturity bands, if used, should be descriptive: 0 to 5 foundational, 6 to 11 developing, 12 to 15 operational, and 16 to 18 linked. These cut points are design choices to be tested for stability, not regulatory thresholds or estimates of safety.

Four scoring safeguards prevent inflation:

- **Evidence beats assertion:** “implemented” requires an artifact type, owner, and last-use period.

- **Current beats historical:** evidence must apply to the focal model version or a controlled product family.
- **Linked beats adjacent:** a complaint system and model registry earn linkage credit only when identifiers connect them.
- **Unknown is not no:** unknown answers remain visible and are not silently treated as mature or absent.

Clinical Validation and Data Governance

A medical device AI clinical validation benchmark

Clinical validation is ongoing scientific assessment, not a one-time model metric. DECIDE-AI defines clinical evaluation as ongoing activities that analyze clinical data using scientific methods (bmj.com). A 2025 JAMA Health Forum study offers a reproducible starting taxonomy by classifying public evidence as none, retrospective dataset, or prospective trial (jamanetwork.com). The survey extends that taxonomy without equating publication absence with operational absence.

For each product, the clinical-validation module records:

- **Study timing:** retrospective, prospective observational, interventional, or post-deployment.
- **Independence:** development site, separate internal site, external collaborator, or fully independent evaluator.
- **Data separation:** whether clinically relevant testing was independent from training data, consistent with IMDRF's principle (imdrf.org).
- **Settings:** number and type of sites, geography, care setting, equipment, workflow, and time period.
- **Endpoints:** prespecified primary metric, comparator, uncertainty interval, and failure criteria.
- **Subgroups:** clinically relevant strata, sample size, performance estimate, uncertainty, and action on disparity.
- **Human factors:** standalone model performance and performance of the combined human-AI team.
- **Version binding:** model, code, data and user-interface versions actually evaluated.

External validation means using the existing model without modifying it (nature.com). It should not be inferred merely because data came from another site. If a model was retuned, threshold-adjusted, or otherwise changed before evaluation, the benchmark records adaptation and subsequent validation separately. IMDRF says the extent of external validation should be risk-proportionate (imdrf.org); the benchmark therefore reports the practice rather than imposing a universal site count.

Subgroup analysis should identify the denominator, metric, uncertainty, and decision rule. TRIPOD+AI calls for performance estimates with confidence intervals for key subgroups (tripod-statement.org), and a peer-reviewed review recommends analysis by population subgroup or problematic use case (nature.com). A checked box without those fields earns only level 1.

Data governance evidence

The data module asks teams to produce provenance, permitted-use basis, cohort rules, labeling method, quality checks, partitions, transformations, access history, version identifiers, and retention decisions. WHO says health-data governance should support ethically sourced, representative, bias-aware AI data (who.int).

IEC PAS 63621 highlights metadata completeness, representativeness, and validity periods (iec.ch). These become survey evidence fields, not generic policy questions.

Missing data must stay visible. TRIPOD+AI requires the handling of missing data and reasons for omission (tripod-statement.org), while CONSORT-SPIRIT asks for enough detail to reproduce missing-data handling (consort-spirit.org). The benchmark consequently separates “not collected,” “not applicable,” “unknown,” and “prefer not to answer.”

PCCPs and Software Change Control

Status, scope, and evidence

An AI medical device predetermined change control plan is not simply a roadmap. The joint FDA, Health Canada, and Medicines and Healthcare products Regulatory Agency principles limit changes to the device’s intended use or purpose (gov.uk) and require clinically justified performance methods (gov.uk).

The questionnaire distinguishes five PCCP states:

- **Not planned:** no product-specific PCCP drafting has started.
- **Drafting:** scope or modification protocol is in development.
- **Submitted:** included in a marketing submission, with review outcome pending.
- **Authorized, unused:** established through marketing authorization, but no covered modification has been released.
- **Authorized, executed:** at least one covered modification has completed protocol, release, and monitoring steps.

That separation is essential because FDA says it does not authorize a PCCP during a Pre-Submission (fda.gov) and defines an authorized plan as one established through marketing authorization (fda.gov). “Discussed,” “planned,” and “authorized” cannot be merged.

PCCP medical device AI best practices

The benchmark evaluates operational substance through the following artifacts:

- **Modification boundary:** model parameters, inputs, outputs, user interface, populations, sites, or performance specifications covered.
- **Protocol:** data management, retraining and performance evaluation, which FDA identifies as core components (fda.gov).
- **Acceptance criteria:** scientifically and clinically justified performance methods and metrics (gov.uk).
- **Impact assessment:** benefits, risks, affected users, labeling and workflow consequences.
- **Release evidence:** protocol version, approver, evaluation result, deployment identifier, communication and rollback readiness.
- **Monitoring:** modification-specific real-world monitoring where applicable (fda.gov).
- **Transparency:** stakeholder awareness of performance before and after changes (gov.uk).

For every product, the analysis crosses PCCP status with model-change cadence. A frequently updated product with only a draft protocol represents a different investment need from a locked model with no planned modification. The cross-tab publishes raw counts and missing answers, never an implied quality ranking.

Postmarket Monitoring and Feedback Loops

MedTech AI postmarket monitoring begins with ownership and an observable threshold. IMDRF makes deployed-model performance monitoring a Good Machine Learning Practice principle (imdrf.org) and NIST calls for clearly defined responsibilities for ongoing monitoring and periodic review (nist.gov). The survey asks for the accountable owner, monitored population, metric, threshold, window, review cadence, escalation path, and last threshold test.

For machine learning medical device performance monitoring, the minimum record is not “drift monitored.” It includes:

- **Input shift:** changes in modality, site, equipment, protocol, prevalence, missingness, or population composition.
- **Output shift:** changes in score distributions, abstention, alert volume, overrides, and uncertainty.
- **Performance:** clinically relevant discrimination, calibration, error rate, operational outcome, and subgroup behavior where labels permit.
- **Threshold logic:** static, seasonal, risk-based, or statistically learned, with rationale and alert owner.
- **Latency:** time from event to data availability, alert, triage, investigation start, disposition, and closure.
- **Response:** continue observation, investigate data, change workflow, retrain, roll back, communicate, or escalate.

Dataset shift is a change in the composition of model input data (nature.com). It is not automatically performance degradation. The medical device AI model drift monitoring module therefore records a signal and its investigation outcome separately. No universal time-to-investigate target was found in the authoritative sources reviewed. The benchmark should publish the observed distribution, such as median and interquartile range, without labeling a percentile as compliant.

Complaint and field-action feedback must connect operational systems. Current 21 CFR 820.35 requires records of complaint review, evaluation, and investigation (ecfr.gov) and explicitly includes corrections or corrective actions (ecfr.gov). Health Canada identifies surveillance, complaint handling, and reporting as possible monitoring-plan elements (canada.ca). The survey tests whether an investigation can retrieve the deployed model, configuration, affected dataset or cohort, monitoring signals, change record, and disposition.

Model and Data Traceability

Traceability asks whether a team can reconstruct what ran, with which data and configuration, under which approval, at a specific time. DECIDE-AI defines a version as a unique reference to an AI system and its components at one point in time (bmj.com). A peer-reviewed framework recommends logging predictions,

model version, input data, and use practices (nature.com). Health Canada names version tracking and traceability in PCCP update procedures (canada.ca), while the EU's joint AI Board and Medical Device Coordination Group guidance points to system-performance logs for high-risk AI systems (europa.eu).

The minimum traceability chain contains:

- **Product identifier:** product, regulatory submission or authorization identifier, and configuration.
- **Software identifier:** source revision, build, dependencies, environment and deployment package.
- **Model identifier:** architecture, weights, hyperparameters, threshold and model-card version.
- **Data identifier:** training, tuning, validation and monitoring dataset versions plus transformations.
- **Decision identifier:** review, approval, exception, risk assessment, and applicable PCCP or change order.
- **Runtime identifier:** site, installation, deployment date, active interval and retirement date.
- **Event identifier:** prediction or aggregate log, monitoring signal, complaint, investigation and action.

IEC PAS 63621 includes data versioning and traceability among AI-enabled medical-device lifecycle considerations (iec.ch). IEC 62304 supplies a common framework for medical-device software lifecycle processes (iec.ch), and ISO 10007 applies configuration-management guidance from concept through disposal (iso.org). The benchmark does not prescribe a tool. It asks whether identifiers are stable, relationships are queryable, and a sampled event can be reconstructed.

Analysis of Key Segments

Segmentation should answer operational questions while avoiding unstable small cells. The primary comparisons are device class, pathway, modality, company stage, and product authorization state. Secondary comparisons include update cadence, deployment model, and respondent role. Each table must show raw n, item denominator, missing n, suppression markers, and whether weights are used.

Table 2 defines the principal publication outputs. It is a reporting specification, not a table of uncollected percentages.

Analysis	Rows and columns	Required output	Decision supported
Practice adoption	Six capabilities by evidence level	Raw n, item denominator, missing n, percentage only after collection	Locate the broadest evidence gaps
Clinical evidence by pathway	Evaluation design and external-site status by 510(k), De Novo, PMA, other or not yet selected	Raw n, suppressed small cells, no causal interpretation	Target validation investment before submission
PCCP by change cadence	Five PCCP states by locked, periodic, frequent, or unknown update cadence	Raw n and row denominator	Test whether change governance matches operating cadence
Monitoring ownership	Accountable function by metric, threshold, review cadence and escalation path	Raw n and role-overlap notes	Resolve monitoring RACI gaps

Analysis	Rows and columns	Required output	Decision supported
Signal investigation time	Detection-to-triage, start, disposition and closure intervals	n, median, quartiles, range, missing n	Identify process latency without inventing a compliance target
Authorization-state comparison	Authorized versus premarket products	Only if both groups clear the suppression threshold and composition is disclosed	Distinguish lifecycle-stage patterns from market-wide claims

These analyses do not imply causality. A higher rate of external-site testing in one pathway could reflect device risk, evidence expectations, modality, company stage, or respondent mix. TRIPOD+AI recommends reporting characteristics overall and by data source or setting where applicable (tripod-statement.org). The benchmark should publish cross-tabs and uncertainty, then label adjusted analyses as exploratory unless prespecified.

Authorized and premarket products should be compared only when the sample supports it. The authorized group must identify pathway and final-decision identifier where possible, while the premarket group reports intended pathway as intended, not achieved. FDA defines a product code as a three-character identifier (fda.gov); that field can support reproducible specialty joins without inferring product quality.

Data Analysis and Evidence

Public-data appendix

The appendix should download and hash the FDA AI-enabled-device CSV on the publication date, preserve the unmodified file, and publish transformation code. As accessed on **September 19, 2026**, the file exposed final-decision date, submission number, device, company, lead panel, and primary product code (fda.gov). The first record's decision date was **June 29, 2026** (fda.gov), and FDA says the page is ordered in reverse chronological order by final decision (fda.gov).

Those dates do not establish a complete census. FDA explicitly says the list is not comprehensive (fda.gov) and says identification relies primarily on AI-related terms in summaries or classifications (fda.gov). Accordingly, the appendix reports **snapshot date, maximum final-decision date, row count, duplicates, missing fields, pathway parsing rules, and revision history**. It never treats row count as the number of all AI medical devices.

Survey estimates and scoring

The cleaned survey dataset should carry four counts for every item: eligible records, answered records, missing records, and excluded records. AAPOR permits precision measures for nonprobability surveys only when the underlying model and calculation are documented (aapor.org). If the first wave lacks a defensible weighting model, publish unweighted counts and percentages with clear denominators. Do not use conventional margins of sampling error as though the sample were probability-based.

Quality checks should include:

- **Role confirmation:** exclude or separately label respondents without direct product knowledge.

- **Duplicate review:** flag matching nonidentifying product, role, timing and response-pattern keys.
- **Logic validation:** check authorization status against pathway language and PCCP status against evidence fields.
- **Missingness:** publish missing n for every metric and reasons where captured.
- **Suppression:** apply the predeclared primary and complementary rules before releasing cross-tabs.
- **Sensitivity:** rerun headline results for high-evidence-proximity respondents and complete cases.
- **Reproducibility:** regenerate every table from the released aggregate file and scoring code.

The scoring analysis publishes the distribution of each capability and the total, but the six-dimensional profile remains primary. Report the median and quartiles only after collection, with raw n. Do not calculate a percentage from a cell that has been suppressed, and do not reverse-engineer suppressed values from totals. The benchmark questionnaire, codebook, scoring rules, aggregate tables, and public-data script should be downloadable together.

Implications and Future Directions

The first investment decision is not “raise the total score.” It is to close the highest-consequence evidence break. A level-0 validation record before submission, an unowned production signal, or an unreconstructable deployed version deserves attention before polishing a mature documentation area. The next priority is linkage: monitoring becomes more actionable when a signal can reach the affected model, cohort, complaint, investigation and authorized change basis.

Table 3 translates the rubric into a 12-month action sequence. “A” denotes accountable and “R” responsible; supporting functions will vary by organization.

Horizon	Priority action	Evidence of completion	Typical A / R
0 to 90 days	Baseline all six capabilities on one focal product	Scored artifact inventory, named owners, missing-evidence register	A: product or quality leader R: cross-functional benchmark owner
0 to 90 days	Freeze identifier and denominator conventions	Product, model, dataset, deployment and survey codebook approved	A: quality R: data and software leads
3 to 6 months	Close validation and data-governance gaps	Version-bound protocol, external-validation rationale, subgroup plan, provenance records	A: clinical R: clinical, data and biostatistics
3 to 6 months	Align PCCP status with actual change cadence	Status verified, modification boundaries, protocol, acceptance and rollback evidence	A: regulatory R: regulatory and software
6 to 9 months	Operationalize monitoring and investigation timing	Named owner, tested thresholds, signal log, measured triage and closure intervals	A: postmarket or quality R: machine learning operations and quality
9 to 12 months	Connect complaints, monitoring, versions and changes	Sampled end-to-end trace passes, exceptions corrected, governance review recorded	A: quality R: quality, software, postmarket and regulatory

The matrix emphasizes measurable completion. NIST describes an AI inventory as an organized database of system or model artifacts (nist.gov), while the UK National Cyber Security Centre frames configuration management as tracking changes, version control, and reproducibility (ncsc.gov.uk). A lightweight linked inventory can therefore create more value than a large policy document that cannot answer which version ran.

Future editions should keep core questions stable, version every change, and publish a bridge for revised variables. Longitudinal reporting should distinguish repeated organizations from repeated product programs without exposing identities. Any year-over-year change should show both years' raw n, respondent composition, denominator, and sensitivity analysis. The public-data appendix should be rerun from a dated snapshot rather than silently updated in place.

Frequently Asked Questions (FAQs)

What are the most useful AI-enabled medical device quality metrics?

The most useful metrics connect evidence to action: external-site and prospective validation status, subgroup coverage, dataset provenance completeness, PCCP state, percentage of deployed versions reconstructable, monitored metrics with tested thresholds, time from signal to triage and closure, and percentage of complaints linked to a model version. Each needs raw n, denominator, owner, and evidence artifact. A total maturity score is secondary.

How should clinical validation of AI medical devices be benchmarked?

Record study timing, site independence, data separation, population and setting, prespecified endpoints, uncertainty, subgroups, human-AI workflow performance, missingness, and the exact version tested. IMDRF calls for evaluation of the combined human-AI team (imdrf.org), and DECIDE-AI's consensus process involved 151 experts from 18 countries and 20 stakeholder groups (bmj.com). External testing should be risk-proportionate, not reduced to a universal site count.

What distinguishes planned from implemented PCCP capability?

A draft, Pre-Submission discussion, submitted plan, authorized plan, and executed authorized change are different states. Implementation evidence includes the applicable protocol version, evaluation output, approval, release identifier, communication, monitoring, and rollback readiness. Health Canada similarly identifies version tracking and control as traceability elements (canada.ca).

How should model drift be monitored?

Monitor input composition, output distributions, clinically meaningful performance, subgroup behavior, operational context, and data latency. Define an owner, window, threshold, escalation and investigation workflow. Do not call every distribution change degradation. Record the signal, affected version and cohort, evidence reviewed, disposition, action, and closure time.

Can authorized and premarket products be compared?

Yes, if both groups have adequate unsuppressed sample sizes and their pathway, modality, class, stage and respondent composition are disclosed. The comparison should remain descriptive. Premarket “intended pathway” must not be reported as an achieved authorization, and absence from FDA’s non-comprehensive public list must not be treated as proof of nonauthorization.

Conclusion

The MedTech AI quality benchmark should reveal where lifecycle evidence is thin before submission, diligence, or scale-up. Its value comes from observable practices, explicit denominators, versioned methods, and honest limits, not from a league table. Six capability scores provide a common map, while the underlying artifacts determine what to invest in first.

Clinical validation should remain version-bound, risk-proportionate, externally tested where appropriate, and explicit about subgroups and human-AI use. PCCP reporting must distinguish drafting, submission, authorization, and executed change. Monitoring needs named ownership, tested thresholds, measured investigation intervals, and linkage to complaints, model versions, data, change decisions, and corrective action. Traceability must reconstruct what ran and why.

The annual survey should publish raw counts, changing denominators, missing answers, suppression rules, recruitment coverage, and a downloadable questionnaire, codebook, scoring script, aggregate tables, and FDA snapshot workflow. Its public-data appendix must retain FDA’s own limitation that the device list is not comprehensive. With those controls, the benchmark can support defensible prioritization without implying that respondents represent the whole market or that a maturity score proves product quality.

Source links

Links cited in this article, in order of first appearance. Full addresses are provided for readers using extracted text.

1. https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-enabled-medical-devices
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About IntuitionLabs

IntuitionLabs is an AI consulting, custom software development and data engineering firm serving pharmaceutical, biotechnology, medical-device and other life-science organizations. We work with clinical, regulatory, medical-affairs, commercial, quality and IT teams to connect technology decisions with the work people need to accomplish.

AI consulting and adoption

Our AI enablement services cover readiness assessments, use-case selection, governance and policies, team workshops, adoption measurement and ongoing advisory support. We help organizations structure the information layer behind AI: source material, context, permissions and maintained knowledge that make generated answers useful and reviewable. Private LLM inference and hosted AI options support teams evaluating how to operate AI with appropriate control over their data and infrastructure.

Software, data and life-science workflows

IntuitionLabs develops custom software for pharma and biotech, integrates enterprise systems, and builds data engineering and business intelligence solutions. Areas of focus include AI agents, regulatory research, medical writing, medical affairs, CMC information, competitive intelligence and clinical-document workflows. Our eTMF intelligence work includes cross-system reconciliation and inspection-readiness support.

Enterprise platforms and regulated delivery

We provide Veeva services, application support, managed services, integrations and custom applications, alongside enterprise content work involving platforms such as Egnyte. For regulated workflows, our services include GxP enablement, computer-system validation and software development addressing 21 CFR Part 11 requirements. The applicable controls, validation responsibilities and acceptance criteria are defined for each engagement.

Work with IntuitionLabs

Explore AI enablement, pharma and biotech software development, data engineering and BI, and Veeva services. Contact IntuitionLabs to discuss your workflow, information sources and implementation needs.

IntuitionLabs publishes educational research to help life-science teams make informed technology decisions. Coverage of a product or organization does not imply a client relationship, endorsement or partnership.

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