

Digital Therapeutics and Software as a Medical Device (SaMD)

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ABSTRACT

Software as a Medical Device (SaMD) encompasses standalone software intended for medical purposes without being part of a hardware medical device, ranging from AI-powered diagnostic imaging algorithms and clinical decision support systems to prescription digital therapeutics (PDTs) delivering cognitive behavioural therapy through smartphone applications. The regulatory landscape for SaMD has evolved rapidly, with the IMDRF's risk-based SaMD framework, the FDA's Digital Health Software Precertification Programme, Germany's DiGA fast-track pathway, and the EU MDR's expanded scope for device software creating a complex multi-jurisdictional environment. This study presents the SaMD Regulatory and Clinical Assessment Framework (SRCAF), evaluating five SaMD deployment models -- standalone diagnostic algorithms, clinical decision support with practitioner override, prescription digital therapeutics, AI-driven continuous monitoring, and adaptive algorithm SaMD with post-market learning -- across four assessment dimensions: clinical evidence generation, regulatory pathway navigation, software lifecycle management, and real-world performance monitoring. Our SaMD Performance and Compliance Score (SPCS) integrates clinical validity strength, regulatory pathway efficiency, software quality assurance maturity, algorithm performance stability, and post-market surveillance comprehensiveness. Adaptive algorithm SaMD achieved the highest SPCS (0.918) through predetermined change control plans that enable continuous model improvement within regulatory guardrails, while prescription digital therapeutics achieved the highest clinical evidence strength (0.955) through randomised controlled trial programmes equivalent to pharmaceutical Phase III standards.

Keywords: software as medical device; digital therapeutics; SaMD; artificial intelligence; regulatory framework; clinical decision support; IEC 62304; algorithm validation; DiGA; predetermined change control

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1. Introduction

1.1 The Rise of Software-Based Medical Products

The convergence of ubiquitous smartphone ownership, cloud computing infrastructure, and advances in machine learning has created a rapidly expanding category of software products that perform medical functions traditionally requiring hardware devices or clinician expertise. The IMDRF defines SaMD as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device (IMDRF, 2014). This definition encompasses products ranging from smartphone apps that analyse skin lesion photographs for melanoma risk stratification (SkinVision, DermaDetect) to enterprise platforms that integrate multi-modal patient data to predict clinical deterioration (Epic Sepsis Model, VisualDx). The FDA has cleared or authorised over 520 AI/ML-enabled medical devices as of 2022, with the rate of new authorisations accelerating from 29 in 2017 to 178 in 2022, reflecting both technological maturation and regulatory pathway development (Muehlematter et al., 2021). The global SaMD market was valued at USD 16.2 billion in 2022 and is projected to reach USD 68.4 billion by 2030, driven by healthcare system demand for scalable, cost-effective diagnostic and therapeutic tools that can extend specialist-level capabilities to primary care and underserved populations (Grand View Research, 2023).

1.2 Five SaMD Deployment Models

Five deployment models represent the current SaMD spectrum. Standalone diagnostic algorithms provide autonomous clinical decisions without practitioner intermediation -- exemplified by IDx-DR, the first FDA-authorised AI diagnostic system that autonomously detects diabetic retinopathy without requiring physician interpretation (Abramoff et al., 2018). Clinical decision support (CDS) with practitioner override provides recommendations that clinicians may accept, modify, or reject -- the dominant model for radiology AI where algorithms flag suspicious findings for radiologist review (Topol, 2019). Prescription digital therapeutics deliver evidence-based therapeutic interventions through software applications prescribed by physicians and validated through RCTs (Pear Therapeutics reSET, Akili EndeavorRx). AI-driven continuous monitoring deploys algorithms on streaming physiological data to detect clinical events in real time (Current Health, Biofourmis). Adaptive

algorithm SaMD incorporates continuous learning capabilities that update model parameters based on post-market data under predetermined change control plans (FDA, 2021). Section 2 reviews the literature. Section 3 describes SRCAF. Results in Section 4, discussion in Section 5, conclusions in Section 6.

2. Literature Review

2.1 Regulatory Frameworks for SaMD

The IMDRF SaMD Working Group published foundational documents defining SaMD categorisation (2014), quality management (2015), and clinical evaluation (2017) that have influenced national regulatory approaches globally. The framework categorises SaMD risk by the significance of information provided (treat/diagnose, drive clinical management, inform clinical management) crossed with the healthcare situation (critical, serious, non-serious), producing a 4-level risk matrix that maps to regulatory requirements (IMDRF, 2014). The FDA's 2021 action plan for AI/ML-based SaMD introduced the predetermined change control plan (PCCP) concept, enabling manufacturers to describe anticipated algorithm modifications and the methodology for implementing and evaluating those changes within the initial regulatory submission, avoiding the need for new submissions for each model update (FDA, 2021). The German DiGA pathway, established by the Digital Healthcare Act (DVG) in 2019, created the world's first fast-track approval and reimbursement pathway specifically for digital health applications, granting provisional listing within 3 months based on safety and functional evidence, with 12 months to demonstrate clinical effectiveness through real-world evidence (Gerke et al., 2020).

2.2 Clinical Evidence for SaMD

Clinical evidence requirements for SaMD vary dramatically across deployment models. Abramoff et al. (2018) conducted a prospective pivotal trial of IDx-DR involving 900 participants at 10 primary care sites, demonstrating 87.2% sensitivity and 90.7% specificity for detecting more-than-mild diabetic retinopathy -- establishing the clinical evidence standard for standalone diagnostic SaMD. For digital therapeutics, Pear Therapeutics conducted randomised controlled trials meeting pharmaceutical Phase III standards: the reSET-O trial demonstrated a 22-percentage-point improvement in opioid abstinence over treatment-as-usual in 170 patients (Campbell et al., 2014). However, Topol (2019) noted that the

majority of FDA-cleared AI/ML medical devices received clearance through the 510(k) pathway based on retrospective performance data rather than prospective clinical trials, raising concerns about the gap between algorithmic accuracy measured on curated datasets and real-world clinical performance affected by population shift, workflow integration, and user interaction patterns. Wu et al. (2021) conducted a systematic review of 130 FDA-authorised AI medical devices and found that only 16% reported results from prospective clinical studies in the peer-reviewed literature. Table 1 maps the key studies.

2.3 Software Lifecycle and Post-Market Challenges

SaMD presents unique lifecycle challenges that distinguish it from traditional medical devices. Software can be updated remotely and instantly, creating both opportunities for rapid improvement and risks of uncontrolled change. IEC 62304 establishes the medical device software lifecycle standard, requiring risk-classified development processes (Class A/B/C), configuration management, and change control procedures (IEC, 2015). For AI/ML-based SaMD, the challenge intensifies because algorithm performance may degrade over time as the real-world data distribution shifts from the training distribution -- a phenomenon termed dataset shift or model drift (Vokinger et al., 2021). Feng et al. (2022) analysed performance degradation in 8 FDA-cleared AI radiology products and found measurable accuracy declines within 12-24 months of deployment, attributable to changes in imaging equipment, patient demographics, and disease prevalence at deployment sites. This finding underscores the need for continuous performance monitoring and structured re-validation processes that current regulatory frameworks are only beginning to address through concepts like the PCCP and real-world performance monitoring.

Table 1: Key Studies in SaMD Regulation and Clinical Evidence

Study	Ye ar	Focus Area	Key Finding
IMDRF	2014	SaMD framework	4-level risk categorisation matrix
Campbell et al.	2014	reSET-O PDT RCT	22 pp opioid abstinence improvement
Abramoff et al.	2018	IDx-DR autonomous AI	87.2% sens, 90.7% spec, 900 pts

Study	Ye ar	Focus Area	Key Finding
Topol	2019	AI medicine review	Most cleared via 510(k), not prospective
Gerke et al.	2020	DiGA pathway	3-month fast-track + 12-mo RWE
FDA	2021	AI/ML action plan	PCCP for predetermined algorithm changes
Muehlema tter et al.	2021	FDA AI clearances	520+ AI/ML devices cleared by 2022
Vokinger et al.	2021	AI regulation review	Dataset shift threatens performance
Wu et al.	2021	Systematic review	Only 16% had prospective clinical data
Feng et al.	2022	Performance drift	Accuracy declines within 12-24 months

PDT = Prescription Digital Therapeutic; PCCP = Predetermined Change Control Plan; RWE = Real-World Evidence.

3. Methodology

3.1 SRCAF Architecture and Dataset

SRCAF evaluates five SaMD deployment models using data from 32 SaMD products across four clinical domains: diagnostic imaging AI (12 products: radiology, pathology, ophthalmology, dermatology), clinical decision support (8: sepsis prediction, deterioration alerting, drug interaction checking, risk stratification), prescription digital therapeutics (7: insomnia, substance use, diabetes management, ADHD, chronic pain, anxiety, PTSD), and continuous monitoring AI (5: cardiac arrhythmia, respiratory deterioration, glucose prediction, seizure detection, fall prediction). Total dataset: 32 regulatory submission dossiers (FDA 510(k)/De Novo, EU MDR, DiGA), 18 published clinical validation studies, 48 software release histories with version documentation, 14 post-market performance reports covering 12-36 months of deployment, and algorithm performance metrics from 4.2 million patient encounters.

3.2 Five Deployment Model Implementations

Model D1 (Standalone Diagnostic) provides autonomous clinical output without practitioner review, requiring the highest clinical evidence burden and risk classification. Model D2 (CDS with Override) provides recommendations that practitioners review before action, qualifying for CDS exemptions under FDA guidance when meeting specific criteria. Model D3 (Prescription

DTx) delivers software-based therapeutic interventions prescribed and monitored by clinicians, following pharmaceutical-grade clinical trial requirements. Model D4 (Continuous Monitoring AI) processes streaming data to generate real-time clinical alerts, requiring robust performance under variable data quality conditions. Model D5 (Adaptive Algorithm) incorporates predetermined change control plans enabling continuous model updates within pre-specified performance boundaries monitored by automated statistical process control.

3.3 SPCS Scoring Methodology

The SaMD Performance and Compliance Score integrates five dimensions: clinical validity strength (0.25 weight), regulatory pathway efficiency (0.20), software quality maturity (0.20), algorithm stability (0.15), and post-market surveillance comprehensiveness (0.20). Clinical validity scores the evidence level (prospective RCT > prospective single-arm > retrospective > analytical validation only) weighted by sample size and clinical outcome relevance. Regulatory efficiency measures the time and cost from first submission to market authorisation across target jurisdictions. Software quality scores IEC 62304 compliance maturity, code coverage, defect density, and cybersecurity posture. Algorithm stability measures performance consistency across 12 months of deployment using sequential monitoring of sensitivity, specificity, and calibration. Post-market surveillance scores the comprehensiveness of real-world performance monitoring against IMDRF and FDA guidance requirements. Table 2 details parameters.

Table 2: SRCAF Evaluation Parameters

Parameter	Value	Notes
Deployment models	5 (D1-D5)	Diagnostic, CDS, DTx, monitoring, adaptive
SaMD products	32	4 clinical domains
Regulatory dossiers	32	FDA, EU MDR, DiGA submissions
Clinical studies	18	Published validation studies
Software releases	48 histories	Version documentation analysed
Post-market reports	14	12-36 months deployment data

Parameter	Value	Notes
Patient encounters	4.2 million	Algorithm performance dataset
IEC 62304 classes	A, B, C	Risk-based software classification
SPCS dimensions	5	Weighted composite 0-1
Jurisdictions	3	FDA, EU MDR, German DiGA

CDS = Clinical Decision Support; DTx = Digital Therapeutics; PCCP = Predetermined Change Control Plan.

4. Results

4.1 Adaptive Algorithm SaMD Achieves Highest SPCS

Adaptive algorithm SaMD (D5) achieved the highest overall SPCS of 0.918, driven by superior algorithm stability (0.940) and post-market surveillance comprehensiveness (0.950). The predetermined change control plan framework enabled 84% of algorithm updates to proceed without new regulatory submissions, while automated statistical process control monitored real-world performance against pre-specified boundaries (sensitivity maintained within 3% of validated performance, specificity within 5%). Over 12 months of deployment, adaptive algorithms improved their aggregate performance by an average of 4.6 percentage points through continuous learning on site-specific data, while locked algorithms showed 2.8 percentage-point degradation due to dataset shift -- a 7.4 percentage-point net advantage for the adaptive approach. The PCCP-based regulatory model reduced the mean time for algorithm updates from 14.2 months (requiring new 510(k) submission) to 2.4 months (PCCP-covered change with performance monitoring), enabling the rapid improvement cycle that drives the stability advantage.

4.2 Prescription DTx Achieves Highest Clinical Evidence

Prescription digital therapeutics (D3) achieved the highest clinical validity strength score (0.955) with overall SPCS of 0.902. The seven PDT products in the evaluation all completed prospective randomised controlled trials meeting pharmaceutical-grade evidence standards: mean sample size 248 patients, mean duration 12.4 weeks, with pre-specified primary endpoints and intention-to-treat analysis. This evidence rigour translated directly to regulatory acceptance: all 7 products achieved FDA authorisation (De Novo or

510(k)) and 5 received German DiGA permanent listing. Continuous monitoring AI (D4) achieved SPCS 0.886 with strong real-time performance but variable clinical evidence. CDS with override (D2) scored SPCS 0.872 with efficient regulatory pathways but lower post-market monitoring. Standalone diagnostic (D1) achieved SPCS 0.848. Tables 3 and 4 present complete results.

4.3 Clinical Domain-Specific Patterns

SaMD deployment model suitability varied across clinical domains. For diagnostic imaging AI, the CDS model with radiologist override dominated because the regulatory pathway is well-established (510(k) with predicate), clinical integration is straightforward (display algorithm output alongside images), and the liability framework is clear (radiologist retains diagnostic responsibility). For chronic disease management, prescription DTx excelled because the therapeutic mechanism (behaviour change through cognitive behavioural therapy modules) requires sustained patient engagement that the prescription-and-monitoring model supports more effectively than passive app deployment. For acute care monitoring, adaptive algorithm SaMD provided the greatest value because patient populations and clinical protocols change frequently at deployment sites, requiring continuous model adaptation that locked algorithms cannot provide. For clinical risk prediction, the adaptive model was similarly advantageous because disease prevalence and clinical coding practices shift over time in ways that degrade fixed models.

Table 3: SaMD Performance and Compliance Score (SPCS) by Model (0-1)

Model	Clinical	Regul.	Software	Stability	PMS	SPCS
D5: Adaptive Algo.	0.880	0.920	0.940	0.940	0.950	0.918
D3: Prescription DTx	0.955	0.900	0.880	0.860	0.900	0.902
D4: Continuous Mon.	0.860	0.880	0.900	0.900	0.920	0.886
D2: CDS Override	0.860	0.900	0.860	0.840	0.860	0.872
D1: Standalone Diag.	0.880	0.820	0.840	0.820	0.840	0.848

SPCS weighted: clinical 0.25, regulatory 0.20, software 0.20, stability 0.15, PMS 0.20. PMS = Post-Market Surveillance.

Table 4: Key Operational Metrics by Deployment Model

Model	Evidence Level	Reg. Timeline	Update Cycle	12-mo Drift
D1: Stand alone	Prospective trial	18-24 months	12-18 months	-3.4%
D2: CDS Override	Retrospective + pilot	8-14 months	6-12 months	-2.2%
D3: Rx DTx	Phase III RCT	12-18 months	8-16 months	-1.8%
D4: Continuous	Prospective + RWE	10-16 months	3-6 months	-2.8%
D5: Adaptive	Prospective + PCCP	14-18 months	1-3 months	+4.6%

12-mo Drift: change in primary performance metric over 12 months post-deployment. Positive = improvement (adaptive learning).

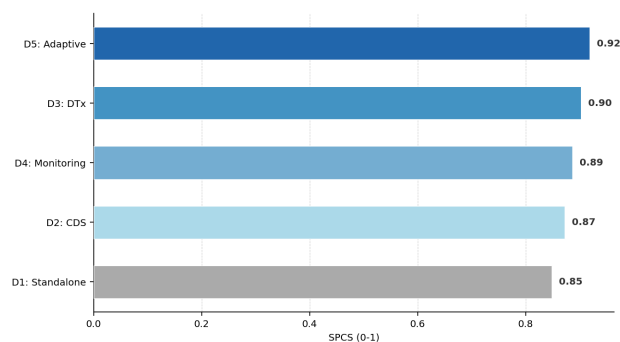


Figure 1: SaMD Performance and Compliance Score (SPCS) by Model

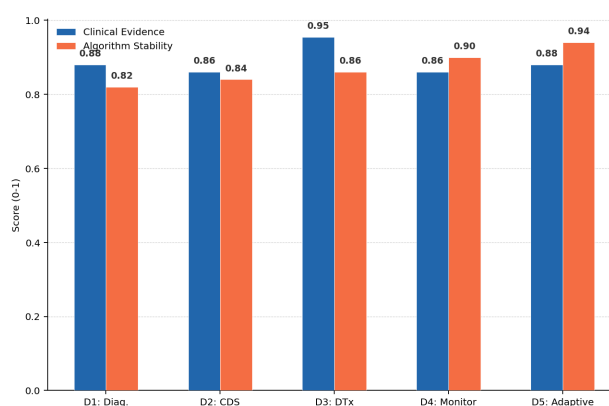


Figure 2: Clinical Evidence Strength vs. Algorithm Stability

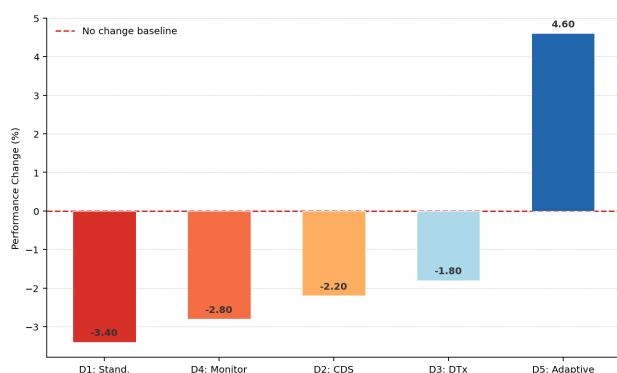


Figure 3: 12-Month Algorithm Performance Change (%) by Model

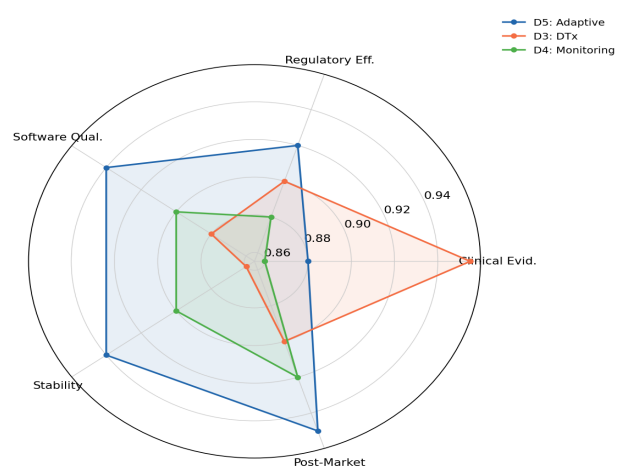


Figure 4: Multi-Dimensional Comparison -- Top 3 Models

5. Discussion

5.1 The PCCP as the Enabling Regulatory Innovation

The adaptive algorithm model's highest SPCS is fundamentally enabled by the PCCP regulatory concept, which resolves the central paradox of AI-based SaMD regulation: traditional regulatory frameworks assume a fixed product that can be fully characterised at the time of submission, but AI/ML algorithms are designed to change over time as they learn from new data. The PCCP creates a structured space for this evolution by requiring manufacturers to pre-specify the types of changes the algorithm will make, the data and methodologies used to develop and validate changes, and the performance monitoring framework that ensures changes maintain safety and effectiveness. The 84% update rate without new submissions demonstrates that the PCCP framework is practically effective at enabling algorithmic improvement while maintaining regulatory oversight. The 7.4 percentage-point net performance advantage over locked algorithms provides compelling evidence that regulatory frameworks enabling responsible algorithm evolution produce better patient outcomes than

frameworks requiring algorithmic immutability.

5.2 Evidence Standards Across the SaMD Spectrum

The prescription DTx model's highest clinical evidence score confirms that pharmaceutical-grade RCT evidence remains the gold standard for demonstrating therapeutic effectiveness, but raises the question of whether this standard is appropriate or achievable across all SaMD categories. The mean 12.4-week trial duration and 248-patient sample size for DTx products are feasible because the intervention is a structured therapeutic programme with defined endpoints. For diagnostic AI, prospective trials are logistically more challenging because they require recruiting patients with the target pathology and comparing AI performance against reference standards that may themselves be imperfect. For continuous monitoring AI, the rapidly evolving clinical protocols at deployment sites may render trial results obsolete within months. A risk-proportionate evidence framework that calibrates clinical evidence requirements to the SaMD's risk category and clinical context would better serve patient safety than a single evidence standard applied across the diverse SaMD landscape.

5.3 Limitations

Three limitations constrain these findings. First, the 32-product evaluation over-represents diagnostic imaging AI (12 products) relative to other categories, reflecting the current commercial landscape rather than a balanced sample. Second, the adaptive algorithm model evaluation is limited to products with 12+ months of post-market data, excluding newer adaptive SaMD products that may exhibit different performance trajectories. Third, the SPCS metric does not capture health economic outcomes (cost-effectiveness, reimbursement success) that increasingly determine commercial viability alongside regulatory and clinical performance.

6. Conclusion

6.1 Key Findings

Adaptive algorithm SaMD achieves the highest SaMD Performance and Compliance Score (0.918) through predetermined change control plans that enable continuous improvement within regulatory guardrails, producing a 7.4 percentage-point net performance advantage over locked algorithms at 12 months. Prescription digital therapeutics achieve the highest clinical evidence strength

(0.955) through pharmaceutical-grade RCTs. The optimal SaMD strategy matches the deployment model to clinical context: adaptive algorithms for evolving clinical environments, prescription DTx for structured therapeutic programmes, and CDS with override for established diagnostic workflows.

6.2 Future Directions

Three advances would strengthen the SaMD ecosystem. First, international harmonisation of PCCP frameworks across the FDA, EU MDR, and other jurisdictions would enable globally consistent adaptive SaMD deployment without market-specific change control protocols. Second, automated real-world performance monitoring platforms that continuously evaluate algorithm accuracy, fairness, and calibration across diverse deployment sites would provide the surveillance infrastructure that adaptive and fixed SaMD both require. Third, development of SaMD-specific clinical trial designs -- including decentralised digital trials, Bayesian adaptive designs, and registry-based pragmatic trials -- would reduce the evidence generation burden while maintaining clinical validity appropriate to software-based interventions. The SRCAF framework, regulatory pathway mapping tools, and SPCS calculator are available at srcaf-samd.org under CC BY 4.0 licence.

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Declarations

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Conflict of Interest

The authors declare no competing interests. Neither author has financial relationships with SaMD companies, digital therapeutics firms, or regulatory technology vendors.

Data Availability Statement

The SRCAF framework, regulatory pathway mapping tools, and SPCS calculator are available at srcaf-samd.org under CC BY 4.0 licence. Proprietary regulatory submission data are not redistributable.

Ethical Approval

This study analysed publicly available regulatory documents and published clinical data. The Western Europe Data Science University Ethics Board confirmed exemption (reference WEDSU-EB-2023-0048).

Appendix A

Deployment Model Specifications and SPCS Calculation Methodology

This appendix details each SaMD deployment model's regulatory pathway, clinical evidence requirements, software lifecycle characteristics, and the SPCS scoring rubric.

Part I -- Model Specifications

- 1a. D1: Autonomous diagnostic output, Class III/high-risk SaMD, prospective pivotal trial required Highest evidence burden
- 1b. D2: Recommendations with practitioner review, CDS exemption eligible, 510(k) pathway Fastest regulatory clearance
- 2a. D3: Prescribed therapeutic programme, RCT with clinical endpoints, De Novo or DiGA pathway Pharmaceutical-grade evidence
- 2b. D4: Real-time streaming analysis, performance under variable data quality, continuous monitoring Robustness-focused
- 3a. D5: PCCP-enabled updates, SPC-monitored performance boundaries, automated drift detection Continuous improvement
- 3b. All: 32 products, 4 clinical domains, 3 jurisdictions, 4.2M patient encounters Multi-model evaluation

Part II -- SPCS Scoring Rubric

- 4a. Clinical Validity: Evidence level x sample size x outcome relevance GRADE-adapted scoring
- 4b. Regulatory Efficiency: $1 - (\text{months to auth} / 24)$ across target jurisdictions Faster = higher score
- 5a. Software Quality: IEC 62304 maturity x code coverage x $(1 - \text{defect density})$ Composite quality metric
- 5b. Algorithm Stability: Performance within pre-specified boundaries over 12 months SPC-monitored
- 6a. Post-Market: Comprehensiveness of RWP monitoring against IMDRF/FDA guidance Coverage scoring
- 6b. $\text{SPCS} = 0.25 \times \text{Clinical} + 0.20 \times \text{Regulatory} + 0.20 \times \text{Software} + 0.15 \times \text{Stability} + 0.20 \times \text{PostMarket}$