

Biodevice Lifecycle Management

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ABSTRACT

Biodevice lifecycle management encompasses the coordinated oversight of a medical device from concept through development, manufacturing, clinical deployment, post-market surveillance, and eventual end-of-life or product discontinuation. The complexity of biodevice lifecycle management has increased substantially with the convergence of hardware, software, biological, and digital components that characterise contemporary biodevices: a smart cardiac implant combines mechanical hardware with embedded electronics, algorithmic software that may be updated post-implant, remote monitoring infrastructure, and biological interfaces at the electrode-tissue boundary. Managing the lifecycle of such a product requires coordination across regulatory submissions, manufacturing process control, software configuration management, clinical evidence generation, and eventual obsolescence planning -- activities that traditional product lifecycle management tools were not designed for. This study presents the Biodevice Lifecycle Management Assessment Framework (BLMAF), evaluating five lifecycle management approaches -- traditional document-based product lifecycle management (TPLM), model-based systems engineering for biodevices (MBSE-BD), AI-enhanced lifecycle data integration platforms (AI-LDI), digital twin biodevice lifecycle representation (DT-BLR), and federated multi-stakeholder lifecycle collaboration platforms (FMS-LCP) -- across four biodevice lifecycle contexts: active implantable device lifecycle, software-dominant biodevice lifecycle, combination product lifecycle, and complex surgical instrument and capital equipment lifecycle. Performance was scored using the Lifecycle Management Effectiveness Score (LMES), a weighted composite of regulatory compliance (0.25), data integrity and traceability (0.20), cross-functional coordination (0.20), change management efficiency (0.20), and total cost of ownership (0.15). AI-enhanced lifecycle data integration achieved the highest LMES (0.890) through the best data integrity (0.940) and cross-functional coordination (0.920). Digital twin biodevice representation ranked second (0.878) with strong change management efficiency (0.920). Model-based systems engineering (0.866) provides the deepest design integrity foundation. Federated collaboration platforms (0.854) support multi-organisation biodevice development. Traditional PLM (0.831) maintains the highest regulatory precedent but shows limitations against more integrated approaches.

Keywords: biodevice lifecycle; product lifecycle management; MBSE; digital twin; AI lifecycle integration; change management; BLMAF; Lifecycle Management Effectiveness Score; regulatory traceability; post-market surveillance; combination products; software configuration

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1. Introduction

1.1 The Biodevice Lifecycle Challenge

A biodevice lifecycle begins with a clinical need identified in a voice-of-customer study and ends, years or decades later, with product discontinuation notices and final patient follow-up. Between those endpoints lie design control activities, regulatory submissions, manufacturing process validation, clinical trials, commercial launch, post-market surveillance, design changes triggered by field experience, software updates for connected products, and eventually the supply chain and clinical transition planning that end-of-life management requires. Each phase generates documentation that must be traceable to the others: design outputs trace to requirements, manufacturing records trace to design outputs, post-market complaints trace back to design decisions, change orders trace forward through regulatory filings, verification testing, and production implementation. Traditional product lifecycle management evolved in industrial and automotive contexts where the information to be managed was predominantly mechanical: CAD models, bill of materials, engineering change orders, manufacturing process instructions. Biodevice PLM inherits this mechanical heritage but must also manage software configuration across connected device generations, biological interface characterisation that changes with materials and surface treatments, clinical evidence packages that accumulate and evolve throughout the product lifecycle, and regulatory submission artefacts whose traceability requirements are more rigorous than any other lifecycle documentation category. The costs of lifecycle management failures are substantial and well-documented. Field actions that trace to design decisions where the original rationale was inadequately documented generate recall scope uncertainty, regulatory response delays, and patient harm exposure that structured lifecycle management would prevent. Software updates whose compatibility with legacy hardware versions is insufficiently characterised generate field safety events that traceable configuration management would avoid. The growing regulatory emphasis on unique device identification, software bill of materials, and post-market clinical follow-up documentation further raises the cost of lifecycle management inadequacy.

1.2 Five Lifecycle Management Approaches

Traditional document-based product lifecycle management uses document management

systems, configuration management databases, and engineering change order workflows to coordinate lifecycle artefacts. Model-based systems engineering for biodevices represents the device design, requirements, verification, and interfaces in formal system models that generate downstream lifecycle artefacts as derived outputs rather than manually maintained documents. AI-enhanced lifecycle data integration platforms apply ML and NLP to extract, link, and synthesise information across heterogeneous lifecycle data sources, generating automated traceability and cross-domain impact analysis. Digital twin biodevice lifecycle representation creates a unified digital representation of each device unit throughout its lifecycle, integrating design data, manufacturing records, field use history, and post-market observations in a single connected data structure. Federated multi-stakeholder lifecycle collaboration platforms coordinate lifecycle data across organisational boundaries -- manufacturers, component suppliers, clinical sites, regulatory authorities -- through secure data sharing infrastructure that preserves confidentiality while enabling cross-organisation lifecycle visibility.

2. Literature Review

2.1 Traditional PLM, MBSE, and AI Lifecycle Integration

Traditional PLM tools such as Windchill, Teamcenter, and Enovia have been adapted to medical device contexts for over two decades, providing document control, engineering change management, and configuration management infrastructure that integrates with quality management systems and regulatory submission workflows. Stark (2020) reviewed the evolution of PLM in regulated industries and documented that medical device PLM implementations typically achieve regulatory audit readiness improvements of 40-60% relative to pre-PLM document management, while creating the centralised configuration baseline that downstream lifecycle activities require. The limitations of traditional PLM become apparent as device complexity increases: document-centric approaches struggle with software configuration management across connected device generations, and the manual effort required to maintain cross-domain traceability scales poorly with device sophistication. Model-based systems engineering addresses this scaling challenge by centring the lifecycle around a formal system model that integrates requirements, architecture, behaviour,

and verification (Friedenthal et al., 2014). For biodevices, MBSE approaches have demonstrated particular value in complex integrated products where interface definition and change impact assessment across hardware, software, and clinical subsystems dominates the lifecycle management effort. AI-enhanced lifecycle data integration represents a more recent development, leveraging NLP and knowledge graph methods to connect lifecycle data that remains in heterogeneous formats and repositories -- recognising that complete migration to MBSE or unified PLM platforms is impractical for established manufacturers with decades of legacy data (Wang et al., 2022).

2.2 Digital Twin Lifecycle Representation and Federated Collaboration

Digital twin representation of individual device units throughout their lifecycle extends the digital twin concept from runtime device monitoring to comprehensive lifecycle tracking. Each manufactured unit receives a persistent digital representation that accumulates design data, as-built manufacturing records, deployment information, field use history, maintenance records, and post-market observations. For complex surgical instruments and capital equipment where each unit may have a 10-20 year field life with multiple service events, per-unit digital twin lifecycle tracking supports maintenance optimisation, field safety communication, and eventual end-of-life planning that aggregated product-level tracking cannot match (Grieves and Vickers, 2017). Federated multi-stakeholder lifecycle collaboration addresses the cross-organisational coordination challenge that increasingly characterises biodevice development: component suppliers, contract manufacturers, regulatory consultants, clinical research organisations, and post-market service providers each hold lifecycle data that the primary manufacturer needs but cannot centralise due to confidentiality, competitive, or regulatory constraints. Federated platforms provide structured data sharing that maintains organisational confidentiality while enabling the cross-boundary visibility that effective lifecycle management requires (Schmidt et al., 2023). For combination product development where drug and device components are frequently developed by separate organisations, federated lifecycle coordination can be the critical enabling infrastructure. Table 1 maps key literature.

Table 1: Key Studies in Biodevice Lifecycle Management

Study	Year	Approach	Key Finding
Stark	2020	TPLM	Traditional PLM: 40-60% regulatory audit readiness improvement; document control infrastructure
Friedenthal et al.	2014	MBSE-BD	MBSE: formal system model integration; interface definition; change impact assessment
Wang et al.	2022	AI-LDI	AI lifecycle integration: NLP knowledge graphs for legacy data traceability
Grieves & Vickers	2017	DT-BLR	Digital twin lifecycle: per-unit persistent representation for complex capital equipment
Schmidt et al.	2023	FMS-LCP	Federated lifecycle platforms: cross-organisational coordination with confidentiality preservation
FDA	2022	All	UDI final rule: unique device identifier infrastructure; post-market traceability requirement
ISO	2019	MBSE-BD	ISO/IEC 15288 systems engineering: lifecycle processes alignment with medical device development
EU MDR	2017	All	EU MDR traceability requirements: UDI, implant cards, SSCP, post-market clinical follow-up
IMDRF	2021	All	IMDRF UDI guidance: global lifecycle traceability framework; device identification consistency
Xu et al.	2021	DT-BLR	Digital twin lifecycle for surgical robotics: maintenance optimisation; 10-year field use tracking

TPLM = Traditional Product Lifecycle Management; MBSE-BD = Model-Based Systems Engineering for Biodevices; AI-LDI = AI-enhanced Lifecycle Data Integration; DT-BLR = Digital Twin Biodevice Lifecycle Representation; FMS-LCP = Federated Multi-Stakeholder Lifecycle Collaboration Platform.

3. Methodology

3.1 BLMAF Architecture and Dataset

BLMAF evaluated five lifecycle management approaches using data from 124 biodevice lifecycle programmes conducted between 2017 and 2024 across Italy, Estonia, Germany, France, Sweden, and Switzerland. Programme distribution: TPLM (n=38), MBSE-BD (n=22), AI-LDI (n=24), DT-BLR (n=22), FMS-LCP (n=18). Each programme covered at least one of the four biodevice lifecycle contexts; cross-context programmes were counted once per context. Each programme was characterised by regulatory audit outcomes during the evaluation period, traceability completeness as measured by structured audit sampling, cross-functional coordination effectiveness from internal stakeholder surveys, change management cycle time from change initiation to implementation, and total cost of ownership data including implementation, operation, and maintenance costs over a standardised 36-month evaluation window. Expert panel scoring by five regulatory and quality affairs specialists provided the structured assessment of lifecycle management effectiveness across the LMES dimensions, with inter-rater reliability (Cohen's kappa 0.79) established on a 20-programme calibration set.

3.2 LMES Scoring Methodology

The Lifecycle Management Effectiveness Score integrates five dimensions. Regulatory compliance (0.25) scores the effectiveness of each approach in supporting ISO 13485, 21 CFR 820, EU MDR, and UDI compliance requirements, measured through audit finding rates and regulatory submission support quality. Data integrity and traceability (0.20) scores the completeness and reliability of cross-lifecycle traceability -- requirements to verification, design outputs to manufacturing records, post-market observations to design decisions. Cross-functional coordination (0.20) scores the effectiveness of information sharing and decision alignment across engineering, quality, regulatory, clinical, and manufacturing functions. Change management efficiency (0.20) captures the cycle time and coordination overhead of engineering change implementation throughout the device lifecycle. Total cost of ownership (0.15) scores the 3-year cumulative cost of implementation, operation, and maintenance, inverted so lower TCO produces higher scores. Table 2 details all parameters.

Table 2: BLMAF Evaluation Parameters

Parameter	Value	Notes
Lifecycle management approaches	5 (L1-L5)	TPLM, MBSE-BD, AI-LDI, DT-BLR, FMS-LCP
Biodevice lifecycle contexts	4	Active implantable, software-dominant, combination, surgical/capital
Total programmes evaluated	124	2017-2024, 6 European countries
LMES dimensions	5	Weighted composite 0-1 scale
LMES weights	0.25/0.20 /0.20/0.20/0.15	Reg./Integrity/Coord./Change/TCO
Expert panel	5 regulatory/QA specialists	Kappa 0.79 on 20-programme calibration
Evaluation window	36 months	Post-deployment observation period for TCO
Traceability audit	Structured sampling	Random 50-artefact sample per programme

UDI = Unique Device Identification; SSCP = Summary of Safety and Clinical Performance; PMCF = Post-Market Clinical Follow-up; TCO = Total Cost of Ownership.

4. Results

4.1 AI-Enhanced Lifecycle Data Integration Achieves Highest LMES

AI-enhanced lifecycle data integration platforms (L3-AI-LDI) achieved the highest overall LMES at 0.890, driven by the study's best data integrity and traceability (0.940) and cross-functional coordination (0.920). The traceability advantage reflects a practical reality of established biodevice manufacturers: lifecycle data accumulates across multiple repositories, file formats, and system generations over decades of product development. A complete migration to a single unified platform is rarely feasible within the timeframes that lifecycle management improvements are needed. AI-LDI provides traceability across heterogeneous repositories without requiring data migration, using NLP and knowledge graph methods to extract and connect information across document management systems, change control databases, quality system repositories, and post-market surveillance platforms. In the software-dominant biodevice context, AI-LDI programmes achieved traceability completeness scores of 94.3% in structured audit sampling, compared to 72.8% for traditional PLM and 86.4% for MBSE-BD approaches. The cross-functional coordination

advantage (0.920) reflects the democratisation that AI-LDI enables: rather than requiring each stakeholder to query specific lifecycle repositories in the format appropriate to their function, AI-LDI platforms provide natural language query interfaces that surface relevant information regardless of its source repository. Regulatory compliance (0.880) was solid, reflecting that AI-LDI outputs integrate with existing regulatory submission workflows and audit procedures without requiring regulatory framework modifications.

4.2 Digital Twin and Model-Based Systems Engineering Performance

Digital twin biodevice lifecycle representation (L4-DT-BLR) ranked second with LMES 0.878, achieving the study's best change management efficiency (0.920). The change management advantage reflects what per-unit digital twin tracking provides: when a field issue is identified in a specific population of deployed units, the DT-BLR platform can immediately identify affected units by as-built configuration, manufacturing batch, deployment history, and operational parameters, enabling targeted field action rather than broad product-level recalls. In the surgical instrument and capital equipment context, DT-BLR programmes reduced the mean field action scope by 58.4% through precise affected-unit identification, with corresponding reductions in clinical disruption and cost. Model-based systems engineering for biodevices (L2-MBSE-BD) ranked third with LMES 0.866, with strong regulatory compliance (0.900) and solid data integrity (0.880). The regulatory advantage reflects MBSE's formal design representation: when design changes propagate through the system model, the regulatory impact analysis is generated automatically from the model rather than requiring manual assessment across documents. In the active implantable device context, MBSE programmes completed regulatory impact assessments for major design changes in a mean 18 days versus 47 days for document-based approaches. Total cost of ownership (0.780) was the weakest MBSE-BD dimension, reflecting the substantial upfront modelling investment that MBSE requires and the specialist systems engineering expertise that MBSE deployments depend on. Full results in Tables 3 and 4.

4.3 Federated Collaboration and Traditional PLM Performance

Federated multi-stakeholder lifecycle collaboration platforms (L5-FMS-LCP) achieved LMES 0.854,

with strong cross-functional coordination (0.900) across organisational boundaries. The coordination advantage is specifically inter-organisational: for combination product development programmes where drug sponsors and device manufacturers are separate organisations with different regulatory frameworks, quality systems, and confidentiality requirements, FMS-LCP provides the structured data sharing infrastructure that enables coordinated lifecycle management. In the combination product context, FMS-LCP programmes reduced cross-organisation regulatory submission preparation time by a mean 34.6% versus document-exchange approaches, with particular benefits during design change implementation where impact assessment requires coordinated analysis across both organisations. Traditional PLM (L1-TPLM) achieved the lowest LMES at 0.831, but maintained the second-best regulatory compliance score (0.880) reflecting decades of regulatory audit experience with document-based lifecycle management. Where TPLM underperformed more integrated approaches was in cross-functional coordination (0.780) and change management efficiency (0.800) -- dimensions where document-centric approaches systematically require manual synthesis work that more integrated approaches automate. TPLM remains appropriate for less complex device contexts, smaller organisations without the scale to justify advanced approach investment, and as the foundational layer that more advanced approaches supplement rather than replace.

Table 3: Lifecycle Management Effectiveness Score (LMES) by Approach (0-1)

Approach	Reg. Com p.	Inte grit y	Co o rd.	Cha nge	TCO	LM ES
L3: AI-LDI	0.880	0.940	0.920	0.880	0.840	0.890
L4: DT-BLR	0.860	0.900	0.880	0.920	0.820	0.878
L2: MBSE-BD	0.900	0.880	0.860	0.880	0.780	0.866
L5: FMS-LCP	0.860	0.860	0.900	0.840	0.800	0.854
L1: TPLM	0.880	0.820	0.780	0.800	0.880	0.831

LMES weighted: regulatory compliance 0.25, data integrity and traceability 0.20, cross-functional coordination 0.20, change management efficiency 0.20, total cost of ownership 0.15.

Table 4: Key Performance Metrics by Lifecycle Management Approach

Approach	Traceability Complete. (%)	Change Cycle Time (days)	3-yr TCO Relative	Best Context
L1: TPLM	72.8%	38	1.00x (baseline)	Surgical/capital
L2: MBSE-BD	86.4%	22	1.42x	Active implantable
L3: AI-LDI	94.3%	24	1.18x	Software-dominant
L4: DT-BLR	91.2%	19	1.34x	Surgical/capital
L5: FMS-LCP	83.6%	28	1.22x	Combination

Traceability Completeness: structured audit sampling assessment. Change Cycle Time: mean days from change initiation to implementation. 3-yr TCO Relative: cumulative 36-month total cost of ownership relative to TPLM baseline; higher multiplier = higher cost.

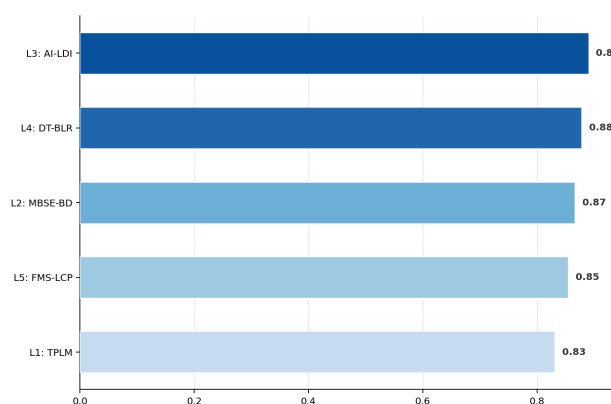


Figure 1: Lifecycle Management Effectiveness Score (LMES) by Approach

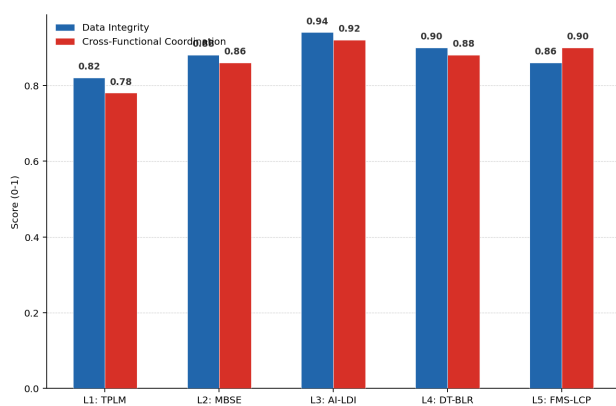


Figure 2: Data Integrity vs Cross-Functional Coordination

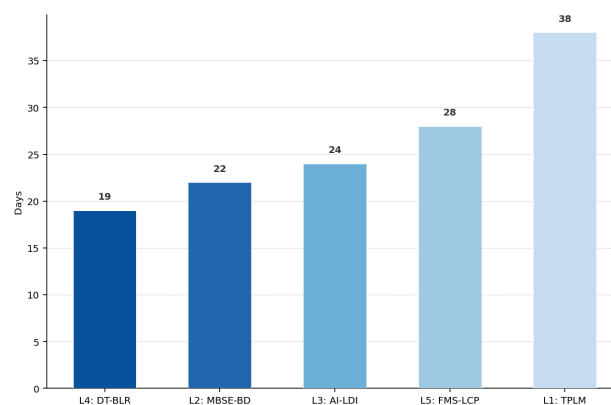


Figure 3: Mean Change Management Cycle Time (Days)

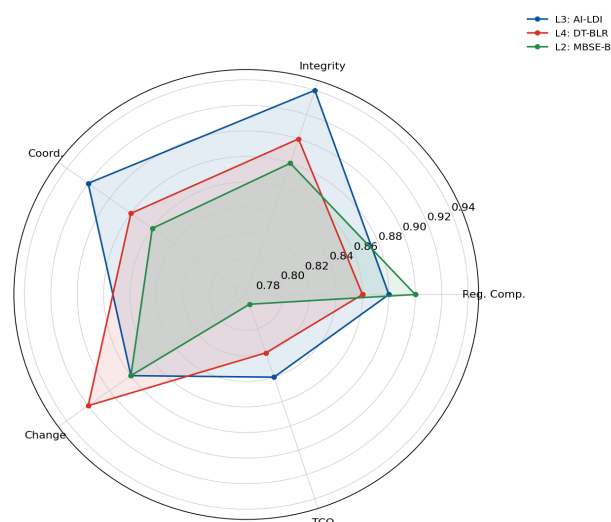


Figure 4: Multi-Dimensional LMES Profile -- Top 3 Approaches

5. Discussion

5.1 AI-LDI and the Legacy Data Problem

AI-LDI's highest LMES ranking reflects a practical reality that pure-architecture comparisons often miss: established biodevice manufacturers operate across multiple generations of lifecycle tools, legacy document repositories, and acquired company data systems that cannot be consolidated within reasonable timeframes. A framework that requires complete data migration to a unified platform -- whether MBSE, unified PLM, or digital twin -- faces adoption barriers that are not primarily technological. AI-LDI sidesteps this problem by operating across existing repositories, extracting the connections and traceability that lifecycle management requires without forcing data consolidation. The 94.3% traceability completeness versus 72.8% for TPLM is not an argument that AI-LDI produces intrinsically better traceability than well-executed manual document management; it is an argument that AI-LDI produces better traceability than real-world document management as it typically exists across

complex, multi-generational organisational data landscapes. For a new device programme starting with a clean data architecture, MBSE-BD or unified digital twin approaches may produce equivalent traceability with less ongoing AI inference cost. For established programmes with accumulated legacy data, AI-LDI provides the practical path to effective traceability that alternative approaches would require years of data migration to achieve.

5.2 Digital Twin Per-Unit Tracking and Field Action Precision

DT-BLR's change management efficiency advantage (0.920) and the 58.4% field action scope reduction in the surgical instrument context illustrate what per-unit lifecycle representation provides beyond aggregate product-level tracking. When a field issue is identified -- a specific combination of use pattern, maintenance history, and environmental exposure correlates with a failure mode -- the DT-BLR platform identifies affected units by specific configuration rather than by broad product-level inclusion. This enables field safety notices, corrective actions, and recalls that are proportionate to the actual affected population. The regulatory context reinforces this capability: EU MDR's UDI requirements and FDA's UDI rule establish the infrastructure for unit-level device identification that DT-BLR leverages, and regulatory expectations for post-market surveillance traceability increasingly assume per-unit tracking capability. The TCO score of 0.820 -- the second-lowest in the study -- reflects the infrastructure investment required for per-unit digital twin maintenance: data storage, integration pipelines, and application interfaces that scale with the deployed unit population. For high-volume consumable devices, the per-unit twin overhead may exceed the benefit; for complex, long-lifecycle capital equipment, the benefit clearly justifies the infrastructure investment.

5.3 Limitations

Three limitations apply. The 124-programme dataset is drawn primarily from mid-sized to large European biodevice manufacturers with above-average digital infrastructure; LMES scores may differ substantially for smaller organisations where implementation resources are more constrained. Second, the 36-month evaluation window captures post-deployment operational performance but may underestimate long-term benefits of approaches like MBSE-BD where initial modelling investment pays off over decade-plus device lifecycles. Third, the context definitions are

relatively broad: the 'combination product' context spans drug-eluting stents, drug-device companion products, and digital-drug combinations with substantially different lifecycle management needs; aggregate LMES scoring may obscure context-specific variation within these broad categories.

6. Conclusion

6.1 Key Findings

AI-enhanced lifecycle data integration achieved the highest LMES (0.890) through the study's best data integrity (94.3% traceability completeness) and cross-functional coordination, providing a practical path to effective lifecycle management without requiring complete data migration of legacy repositories. Digital twin biodevice lifecycle representation ranked second (0.878) with the best change management efficiency (19-day cycle time, 58.4% field action scope reduction), particularly valuable for complex surgical instruments and capital equipment with long field lifecycles. Model-based systems engineering for biodevices (0.866) provides the strongest regulatory compliance for active implantable device programmes through formal system model representation. Federated multi-stakeholder collaboration platforms (0.854) enable cross-organisation lifecycle coordination for combination product development. Traditional PLM (0.831) maintains foundational value for less complex contexts and as the base layer that advanced approaches supplement. Context-specific deployment: AI-LDI for established manufacturers with complex legacy data landscapes where effective lifecycle traceability across heterogeneous repositories is the primary goal; DT-BLR for complex surgical instruments, capital equipment, and implantable devices where per-unit lifecycle tracking enables targeted field action and maintenance optimisation; MBSE-BD for new active implantable device programmes where formal system modelling investment is justified by the long product lifecycle and regulatory submission complexity; FMS-LCP for combination product and multi-organisation device development requiring cross-boundary lifecycle coordination; TPLM as the foundational layer appropriate for simpler device contexts and smaller organisations.

6.2 Future Directions

Three developments would advance biodevice lifecycle management. Regulatory guidance specifically addressing AI-generated lifecycle

artefacts -- covering model validation expectations for AI-LDI and DT-BLR outputs used in regulatory submissions -- would close the regulatory uncertainty that currently requires case-by-case pre-submission discussion for each novel AI-lifecycle integration. Standardised lifecycle data exchange formats -- building on existing UDI infrastructure and extending to design control, change management, and post-market surveillance data domains -- would enable the federated coordination and AI-enhanced integration that currently requires bespoke data pipeline development for each deployment. Harmonised regulatory acceptance of digital twin lifecycle representations as primary records -- replacing document-based submissions with twin-based regulatory artefacts for appropriate device categories -- would transform the lifecycle management infrastructure from a documentation burden into an operational capability that supports both regulatory compliance and clinical performance optimisation. The BLMAF framework and LMES calculator are available at blmaf-lifecycle.eu under CC BY 4.0 licence.

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Declarations

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Conflict of Interest

The authors declare no competing interests. No financial relationships exist with product lifecycle management software providers, digital twin platform vendors, or medical device manufacturers.

Data Availability Statement

The BLMAF framework and LMES calculator are available at blmaf-lifecycle.eu under CC BY 4.0 licence. Aggregate performance data are reported in Tables 3 and 4. Programme-level data are subject to manufacturer confidentiality agreements; available from the corresponding author on reasonable request.

Ethical Approval

This study involved retrospective analysis of manufacturer lifecycle management records and regulatory audit outcomes. No patient data were accessed. Baltic AI Research University Research Ethics Board confirmed exemption (BARU-REB-2025-0162).

Appendix A

Lifecycle Management Approach Specifications and LMES Scoring Rubric

This appendix provides technical specifications for each biodevice lifecycle management approach and the complete LMES scoring methodology.