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SaMD in US and the AI Act

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Software as a Medical Device (SaMD) vs Medical Device Software (MDSW)

SaMD refers to software intended for one or more medical purposes without being part of a hardware medical device. In the United States, the FDA oversees SaMD to ensure it meets safety and effectiveness requirements. Examples include clinical decision support tools, diagnostic apps, and remote patient monitoring software.

In the EU, Medical device software (MDSW) is software that is intended to be used, alone or in combination, for a purpose as specified in the definition of a “medical device” in the medical devices regulation or in vitro diagnostic medical devices regulation.

SaMD in the US

Regulatory Framework

- 21 CFR 820 Quality System Regulation (QSR) often applies, although the FDA has proposed updates (e.g., aligning with ISO 13485)
- Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products- Draft Guidance for Industry and Other Interested Parties (January 2025)
- Artificial Intelligence and Machine Learning Software as a Medical Device Action Plan
- Good Machine Learning Practice for Medical Device Development: Guiding Principles
- Draft Guidance: Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions (April 2023)
- Predetermined Change Control Plans for Machine Learning-Enabled Medical Devices: Guiding Principles (October 2023)
- Final Guidance: Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions (December 2024)

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Key Areas of Compliance

Intended Use and Risk Level
Determines whether the software qualifies as SaMD and guides its regulatory pathway.

Design Controls and Validation
Ensures thorough documentation of requirements, design, verification, and validation activities.

Cybersecurity
Manufacturers must address cybersecurity vulnerabilities, ensuring robust data protection and system integrity.

AI/ML considerations

1. Manufacturers must prepare predetermined change control plans (PCCP) when the system is adaptative.
2. Multi-disciplinary expertise is leveraged throughout the total product life cycle.
3. Good software engineering and security practices are implemented.
4. Clinical study participants and data sets are representative of the intended patient population.
5. Training data sets are independent of test sets.
6. Selected reference datasets are based upon best available methods.
7. Model design is tailored to the available data and reflects the intended use of the device.
8. Focus is placed on the performance of the human-ai team.
9. Testing demonstrates device performance during clinically relevant conditions.
10. Users are provided clear, essential information.
11. Deployed models are monitored for performance and re-training risks are managed.

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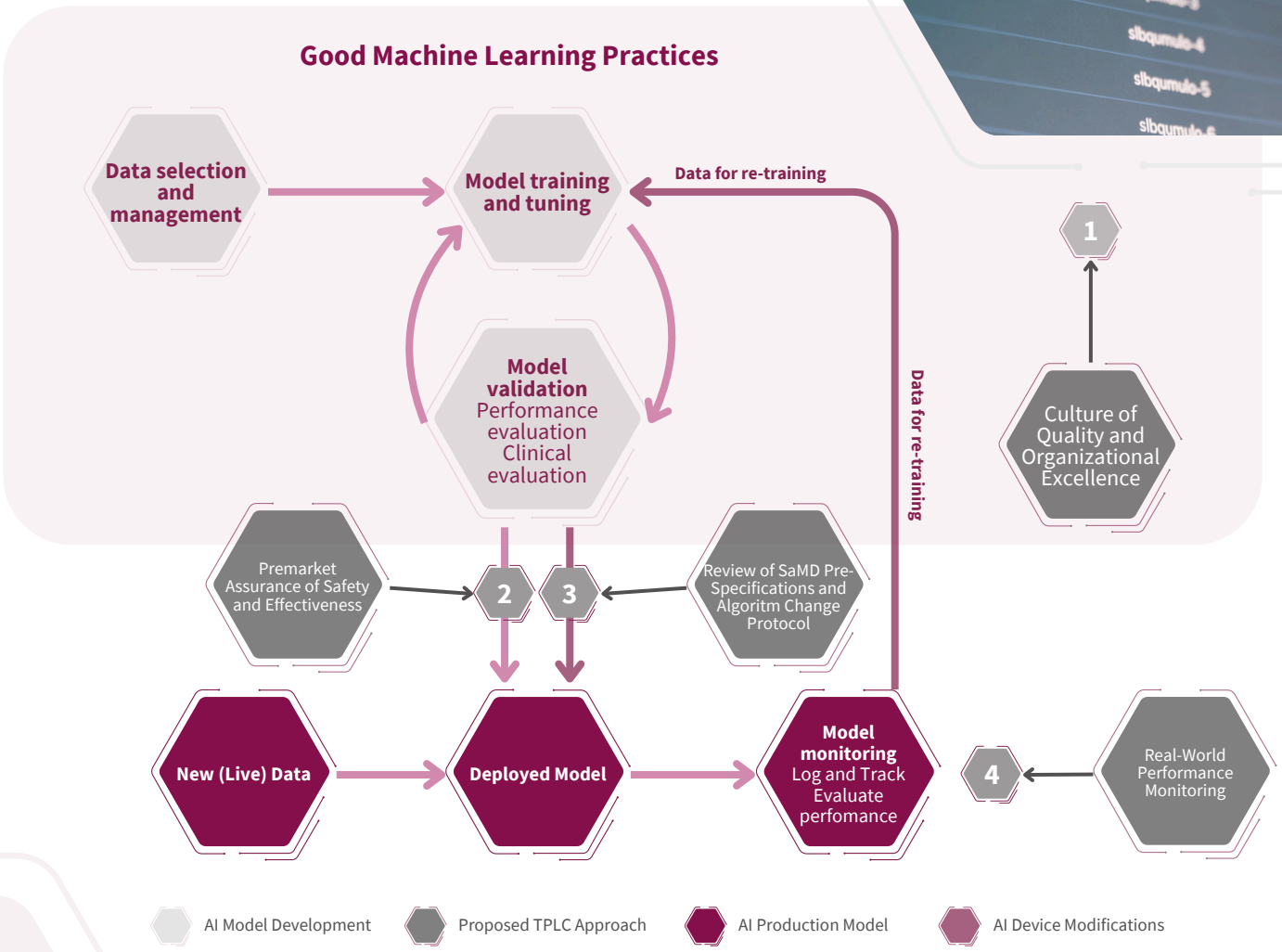

Figure 1: Overlay of FDA's TPLC approach on AI/ML workflow

The AI Act in the European Union

The proposed EU Artificial Intelligence Act (AI Act) sets a regulatory framework for AI-based systems, including those that meet the definition of a medical device or software with potential health impacts.

Classification of AI Systems

- **High-Risk AI Systems:** Medical devices with AI features are typically deemed high-risk, facing strict requirements for testing, documentation, and human oversight.

- **Limited and Minimal Risk:** Face fewer regulatory hurdles but still require transparency and data governance measures.

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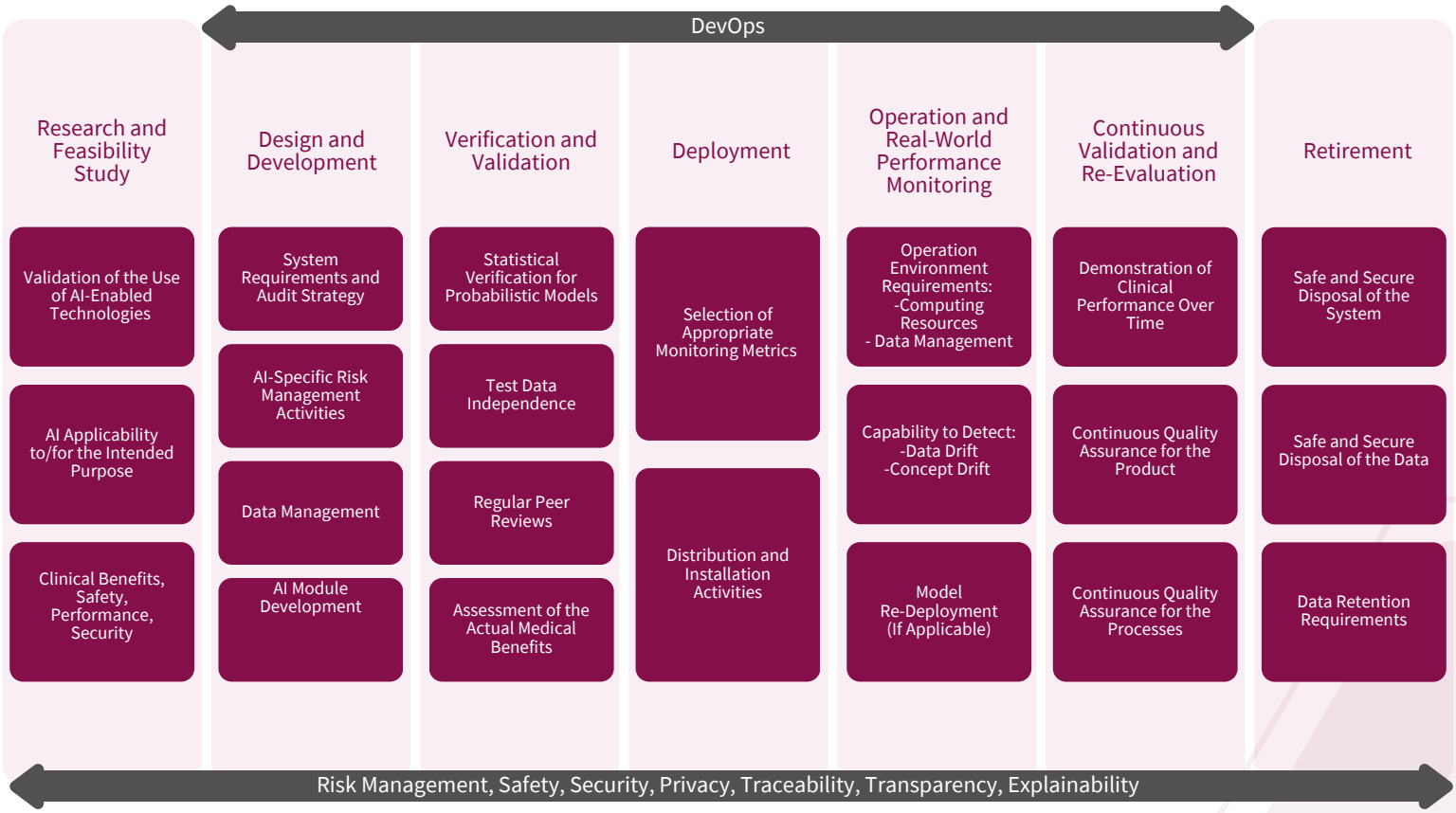
Impact on SaMD Development

- **Additional Compliance Layers:** AI-driven SaMD in Europe must meet both medical device regulations (MDR/IVDR) and the forthcoming AI Act requirements.
- **Continuous Monitoring:** Post-market surveillance of performance, safety, and accuracy is emphasized, particularly for AI that learns and evolves over time.



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Risk Management and Classifications

- **Risk Assessment:** Evaluate how AI or SaMD features could lead to potential harm, considering clinical performance, data integrity, and user interaction.
- **Ongoing Mitigation:** Implement software-based and procedural controls (e.g., audits, user training, fallback modes).
- **New regulation and guidance in the US:** Monitor updates for new legislation updates or FDA guidance on AI Systems.

Documentation and Quality Management

- **Development Plan:** Outline the life-cycle approach, from initial design to decommissioning, ensuring alignment with regulatory expectations in both the US and EU.
- **Testing and Traceability:** Maintain rigorous test plans, traceability matrices, and risk management files to prove compliance and support any audits or inspections.
- **Quality Management System:** For both EU and FDA, ISO 13485 is the gold standard for QMS of manufacturers of MDSW/SaMD, as it was recently integrated by the FDA. Additional QMS considerations for the AI Act need to be added to the ISO 13485 QMS of the manufacturer, with specific procedures (SOPs) for data governance, automatically generated logs, training of algorithms, transparency, human oversight and others.
- **Technical Documentation:** Given the significant difference between US and EU Regulations, the technical dossiers for both territories will likely face important differences and will most probably be kept in separate structures. EU Technical Documentation based on MDR Annex II with additional AI Act considerations will be the foundational document for MDSW, for FDA and SaMD the situation is quite different, depending on the route chosen (510(k), De Novo, PMA, etc.) the dossier format and contents will face unique elements.

Preparing for SaMD/MDSW and AI Adoption

- **Pre-Submissions and Meetings:** Engage early with the FDA and relevant EU bodies to clarify compliance strategies.
- **Monitor Regulatory Updates:** Stay informed of evolving guidance in the US and the final adoption of the AI Act in the EU.
- **Prepare for AI Act certification in the EU.**

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As a Biomedical Engineer with a Master's Degree in Digital Health, Diego has consolidated his experience in Medical Software as Subject Matter Expert (SME) within Asphalion MedTech with significant experience on AI/ML development, programming, software validation and testing, cybersecurity and AI regulation in several territories worldwide.