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Navigating AI in Medical Devices

From Hype to Harmonization

Dr. Andrei Ninu & Sumatha Kondabolu

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Today’s hosts

Andrei Ninu
Head of Software Operations Unit
DQS

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Agenda

1 **Setting the Scene:**
AI in Healthcare & Medical Devices

Market Landscape, Technologies, Trends

2 **Regulatory Landscape:**
Navigating Complexity

Legal Frameworks, Guidelines, Standards

3 **Key Challenges:**
On the path to adoption

Clinical Validation, Transparency, Harmonization

4 **From Risk to Readiness:**
Addressing the Challenges

Strategies for Implementation & Compliance

5 **Using AI for compliance:**
A new way to meet your requirements

Compliance Intelligence

6 **Q&A:**
Get your questions answered

Ask Andrei & Sumatha

1. Setting the Scene

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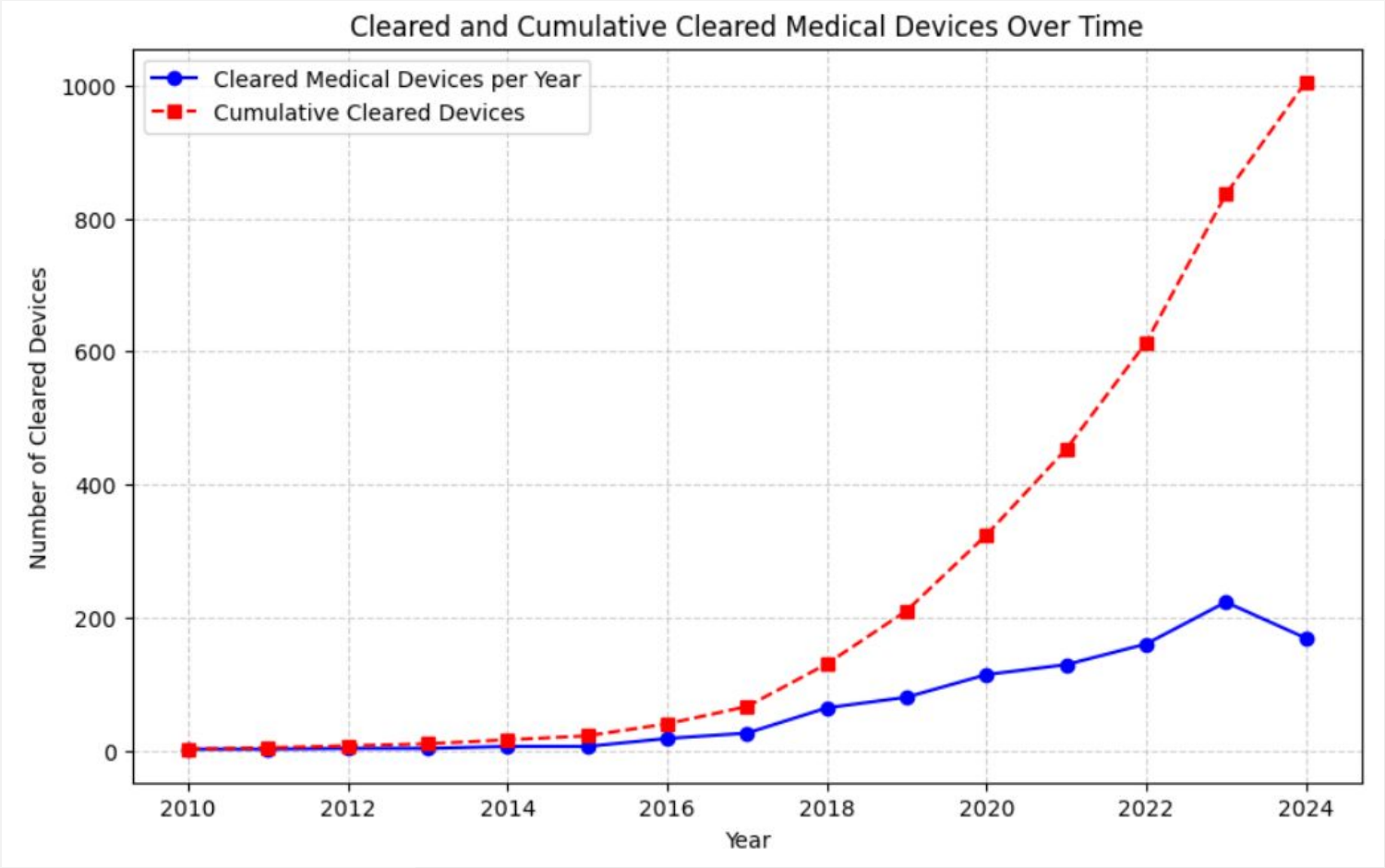
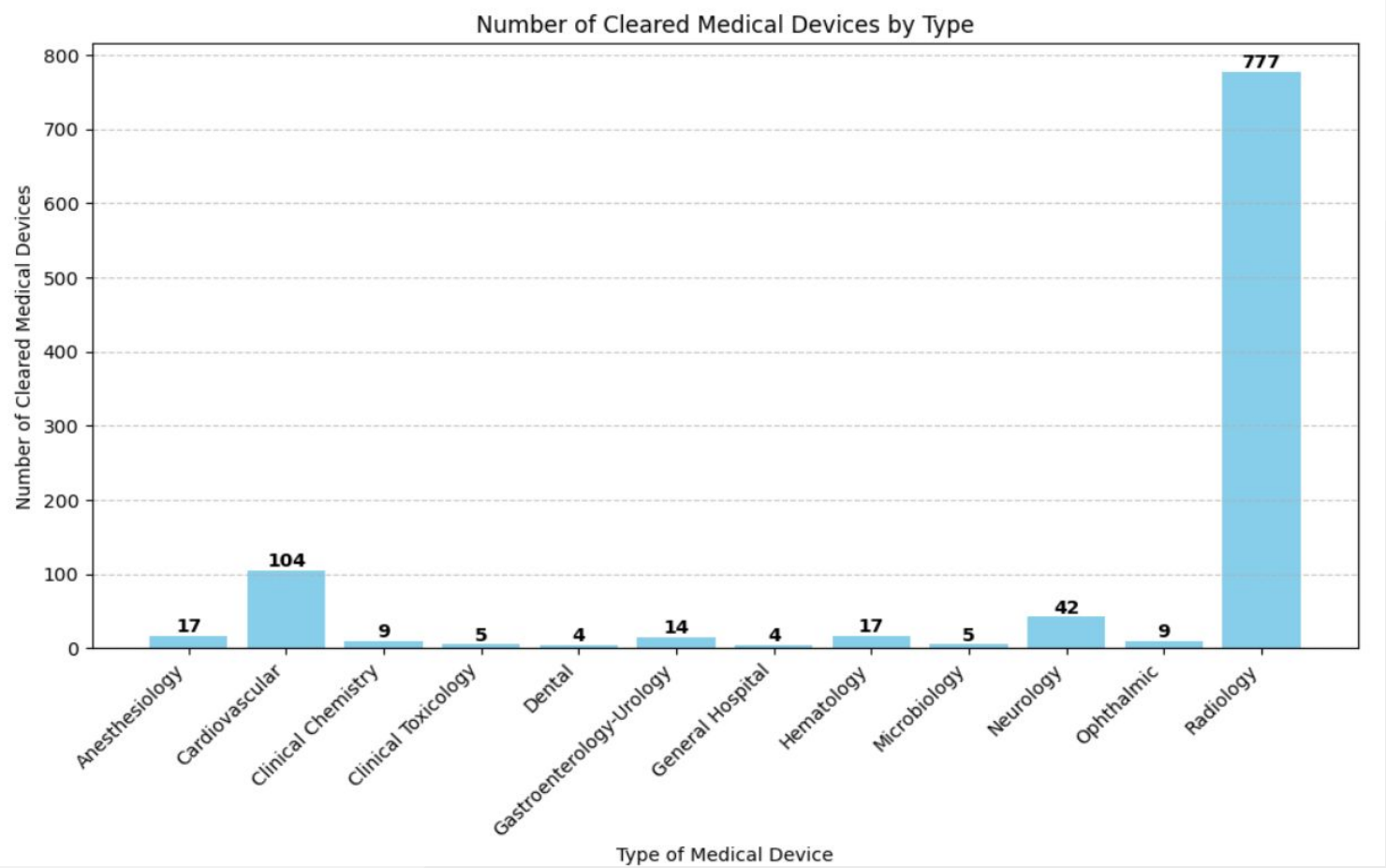
MARKET LANDSCAPE



Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices | FDA

1. Setting the Scene
TECHNOLOGIES



Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices | FDA

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1. Setting the Scene

MARKET TRENDS

AI for Cybersecurity

- Anomaly detection: Identifies unusual behavior that could indicate cyberattacks.
- Adaptive threat response: AI models can learn attack patterns and automatically adjust firewalls or access controls.

AI for Usability

- Predictive user input: AI learns clinician behavior to suggest next steps or autofill repetitive entries.
- Context-aware displays: Interfaces that adjust displayed information based on the user's role, location, or activity.
- Predictive user input: AI learns clinician behavior to suggest next steps or autofill repetitive entries.

AI in Manufacturing and Supply Chain

- Predictive maintenance of manufacturing equipment
- Yield optimization and defect detection
- Supply chain resilience forecasting

AI for Quality and Compliance

- Automated QMS reviews (risk management, audit readiness)
- Gap analysis & evidence collection
- Predictive quality analytics: Identify patterns leading to nonconformities or recalls

1. Setting the Scene

SUMMARY

From hype to real-world impact

Artificial Intelligence is tackling the growing pressures on healthcare systems Worldwide

Short-term:

Most gains will be in efficiency and cost reduction - increase effectiveness of the workflows

Mid- to long-term:

Gains in clinical outcomes as AI becomes embedded in decision-making and personalized care

8 European Medtech Companies who have led the charge in digital health in 2024 | Panda International

2. Regulatory Landscape:

NAVIGATING COMPLEXITY

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Regulatory Landscape

Guidance Docs and Standards

Guidance Documents: **AIB 2025-1 / MDCG 2025-6**

Interplay between the Medical Devices Regulation (MDR) & In vitro Diagnostic Medical Devices Regulation (IVDR) and the Artificial Intelligence Act (AIA) - **June 2025**

Standards:

ISO/IEC 23894:2023

ISO/IEC 42001:2023

AAMI TIR 34971:2023

ISO/IEC 5338:2023

IEC/TR 60601-4-1:2017

IEC 81001-5-1:2021

ISO/IEC TS 4213:2022

ISO/IEC 8183:2023

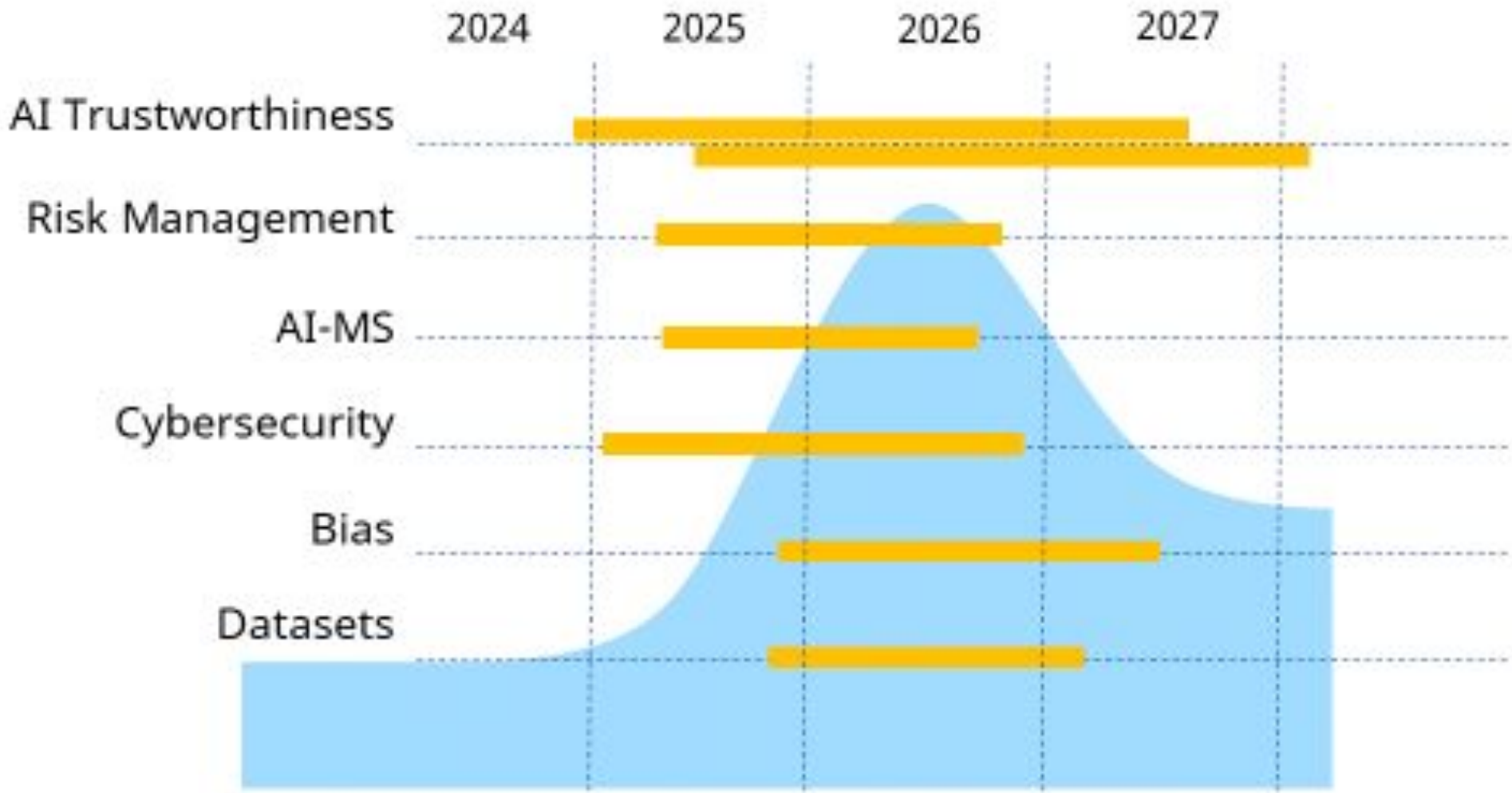
IEC TR 60601-4-5:2021

ISO/IEC 5259-4:2024

ISO/IEC 22989:2022

ISO/IEC TR 24028:2020

JTC 21 – Standards in support of AI Act (2024-2027)



Regulatory Landscape

REQs on AI Systems from MDR

GSPR#41: Performance, Safety, and Intended Purpose
AI-based systems must be validated to consistently achieve their intended purpose under real-world conditions.

GSPR#45: Human Factors and Usability Engineering
Critical to mitigate over-reliance on AI. User interfaces should communicate uncertainty, be adapted to the cognitive load and experience of intended users.

GSPR#46: Performance Stability Over Lifetime
System must remain robust to expected input variances. Monitoring for model drift and environmental impact (e.g., hardware dependencies, cloud latency) is key.

GSPR#15.1: Accuracy and Precision of Diagnostic Outputs
Model performance must be statistically demonstrated (e.g., sensitivity, specificity) in both training and real-world datasets. Stability and performance thresholds must be disclosed.

3. KEY CHALLENGES

On the path to adoption:

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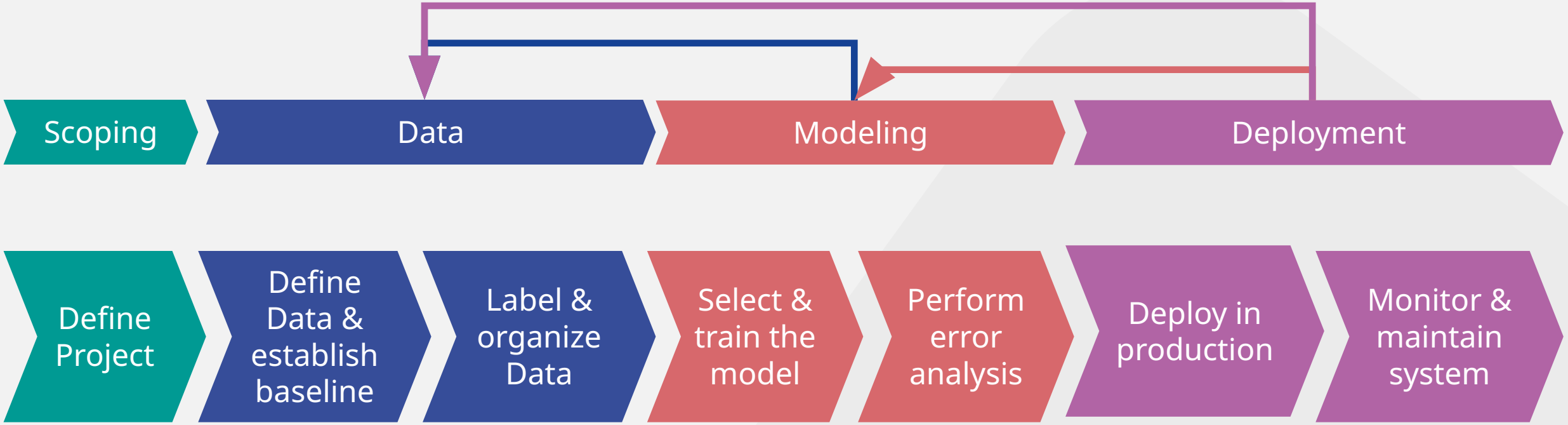
KEY CHALLENGES

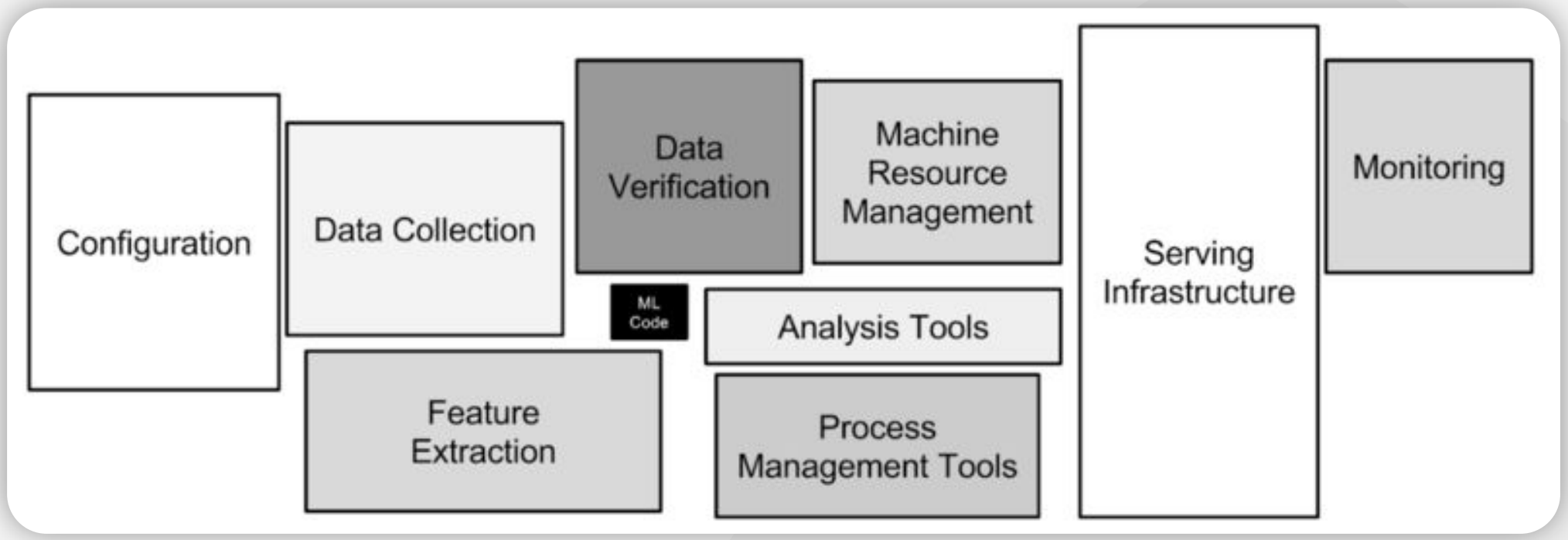
A generic AI lifecycle



Machine Learning | Coursera

The lifecycle

The model is a tiny fraction of an overall AI system



Monitoring Machine Learning Models in Production

KEY CHALLENGES

Inadequate Definition of Intended Use / Purpose
- undefined target population
- missing context of use

Performance Metrics
- inappropriate or insufficient

Ground Truth Definition
- often missing or ambiguous
- not always traceable to clinical consensus/expert annotation
- validity over time

Data Quality
- Non-standardized Data
- Low Sample Diversity
- Label Noise

Dataset Splitting and Data Traceability
- Ambiguous splitting of datasets for training, validation, and testing
- Lack of stratified performance results
- No explanation of inclusion/exclusion criteria
- Missing rationale for dataset sizes and balance

Transparency of Algorithm Architecture
- rationale for algorithm selection
- details on training-validation strategies
- Hyper-parameter tuning approach
- configuration management
- traceability of decisions throughout development

Training Process and Lack of Evidence for Generalizability
- No evidence of model performance on external or representative datasets
- Lack of stratified performance results

KEY CHALLENGES

Traceability as complement to Explainability

- Documented rationale for algorithmic choices
- End-to-end audit trail of data, model versions, and changes
- Ability to reconstruct decisions and outcomes retrospectively

Integrated Management Systems

- Unified risk management across product safety, cybersecurity, and AI lifecycle
- Alignment of regulatory (MDR, AI Act) and quality (ISO 13485, ISO 42001) requirements
- Enhanced efficiency by leveraging common frameworks (Annex SL, HLS)

Terminology Noise

- Substantial Modifications vs Significant Changes
- Inherent Safety (SW)

Validation

- AI enabled Tools
- Continuous validation

PMS/PMCF

- No evidence of model performance on external or representative datasets
- Lack of stratified performance results

Predetermined Changes (FDA vs AI Act)

- No evidence of model performance on external or representative datasets
- Lack of stratified performance results

Addressing the Challenges:

4 FROM RISK TO READINESS

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Key challanges:
the growing GAP

From Risk to Readiness

SOFTWARE OPERATIONS UNIT

Software Operations Unit

Unit within DQS-MED, composed of software experts who work across functions to support all software-related, conformity assessment activities.

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From Risk to Readiness:

DQS strategic involvement

European & International Governance

DQS actively participates in:

- IG-NB subgroups
- AI Act Implementation Forums (e.g. stakeholder workshops, notified body taskforces)
- Joint European standardization efforts (ISO/DIN for Artificial Intelligence and Digital Health

SwOpUnit: driving alignment across all DQS-MED Functions

From Risk to Readiness:

with STRUCTURED DIALOGUES

MDCG 2022-14 encourages notified bodies and manufacturers to oragnise **structured dialogues** before and during the conformity assessment process.

Such dialogues should not be considered consultancy service.

[actors: MDCG, NBO]

Phase 1: Corner Points

Dialog on project corner points:
MD classification, applicable codes,
i.e. Project SetUp

Phase 2: Planning

Evaluation of Planning activities:
Lifecycle, Usability, Clinical, Risk Assessment, Verification/Validation

Phase 3: Evaluation of Evidences

Evaluation of evidences

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5. Using AI for compliance: a new way to meet your regulatory requirements

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Current approaches: fragmented and reactive

Approach	Strengths	Limitations
Manual (spreadsheets, shared drive)	Flexible, low-cost	Labor-intensive, error-prone, hard to scale
eQMS	Familiar, industry-appropriate	Not built with compliance frameworks or for audit readiness
Public AI tools	Fast, accessible	Lacks security, traceability, compliance, industry focus
InfoSec tools	Specialized for cybersecurity	Not designed for life sciences, limited coverage

Demo

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qualio.com/demo-ci

The Road Ahead:

6. Q&A

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Let’s shape the Future of AI-enabled MDs together

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Thank you!