APACMed 10TH ANNIVERSARY

A Decade of Progress

In Partnership With RQS

Mastering the Regulatory Landscape for AI/ML-Enabled SaMD

Gain a Competitive Edge with Confidence in Your AI/ML-Enabled Medical Technology

Tuesday, 4 June 2024

0900-1000 SGT

Register for the webinar now

Cindy Pelou
APACMed Representative
Host

Andrew Wu
VP of Medical Software, GM of APAC Office
Rook Quality Systems

Paul Chua
Cybersecurity Officer, Greater Asia
BD

Manan Hathi
Sr. Manager, Regulatory Affairs, Digital Health Policy
Stryker

Victor Tan
RAQA Manager, APAC Indirect Markets
Intuitive Surgical

About APACMed

WHO WE ARE

The Asia Pacific Medical Technology Association (APACMed) represents **manufacturers and suppliers of medical equipment, devices and in-vitro diagnostics, industry associations and other key stakeholders** associated with the medical technology industry in Asia Pacific.

OUR OBJECTIVE

- As a trade association, our mission is to **improve the standards of care for patients** through innovative collaborations among stakeholders to jointly shape the future of healthcare in Asia Pacific.
- Build and support a **strong regulatory workforce** for MedTech industry and regulators and **drive capacity building initiatives** in partnership with various stakeholders.

About APACMed

360 member companies

60 corporate members

150 Startups

HEADQUARTERS: SINGAPORE
COUNTRY OFFICES: INDIA & CHINA

FUNCTIONAL COMMITTEES

- **Regulatory Affairs** 500+ members
- **Government Affairs & Market Access** 250+ members
- **Digital Health** 300+ members
- **In-Vitro Diagnostics** 130+ members
- **Legal Ethics & Compliance** 150+ members
- **Start-Up & SME** 250+ members

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Speaker Introduction

Andrew Wu

Rook Quality Systems

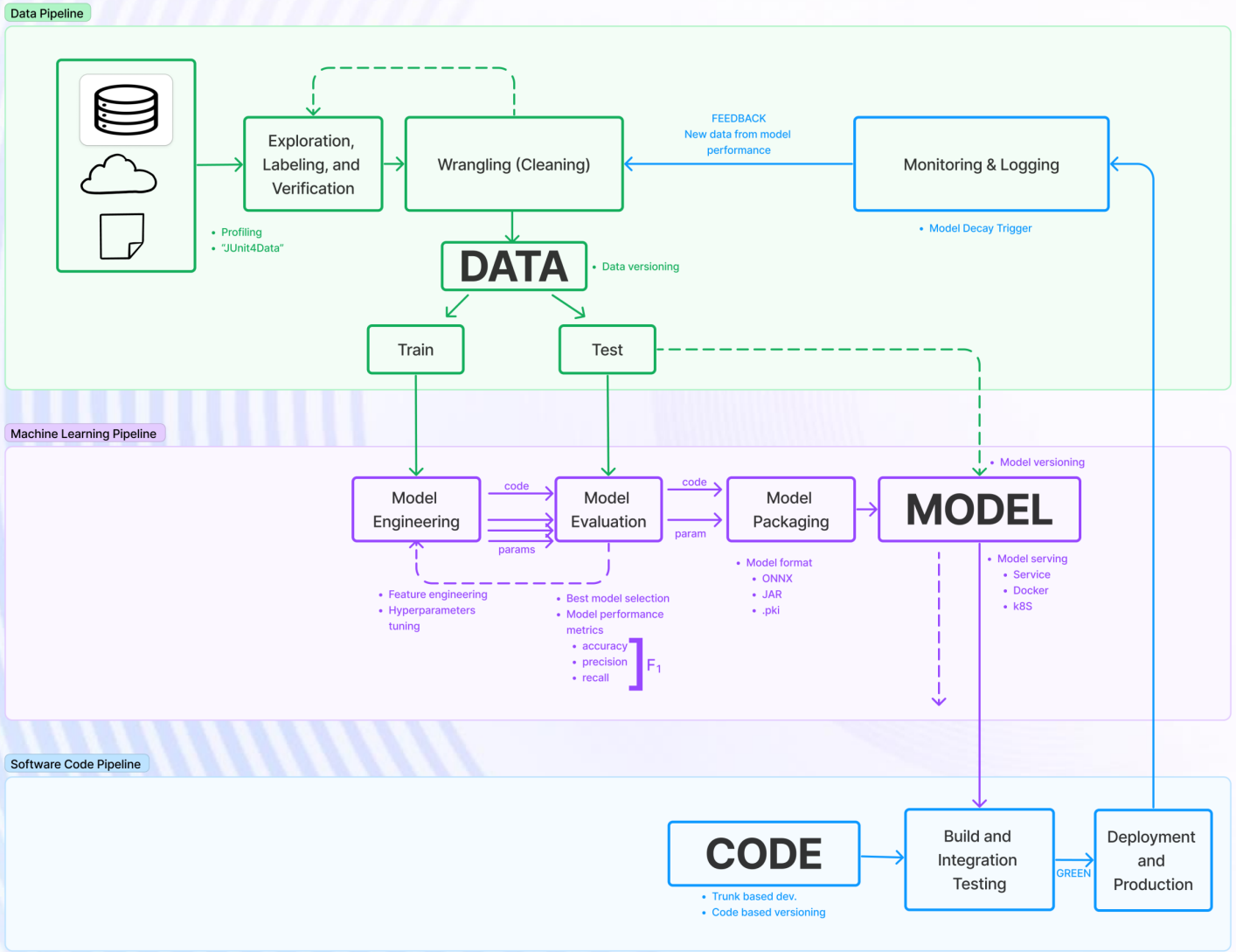
VP of Medical Software, GM of APAC Headquarter

- 12+ years of experience in the medical device and diagnostic industry, with expertise in technical development, quality and regulatory strategy in the SaMD space.
- Extensive experience managing verification and validation testing and strategy for medical device standalone and embedded software.
- Well-versed in navigating international medical device markets, ensuring adherence to international regulatory standards.

Challenges for Regulating AI/ML Solutions

- **Additional considerations for managing data pipeline and ML operations (on top of the SDLC process)**
  - Generalizability across populations and different real-world conditions
  - Security considerations across data, model, and operating system
- **Change management is necessary to maintain the performance of AI/ML devices**
  - Combat concept drift and deploy proper monitoring and maintenance schema
- **Trustworthiness of AI/ML devices**
  - Achieve better interpretability and explainability by end user through validation, model labeling, product labeling

Interaction among Dev Ops, ML Ops, and Data Pipeline



Machine Learning Operations

Software Development Operations

IMDRF SaMD WG
N23
Application of QMS

Reference: [Machine Learning Workflow]

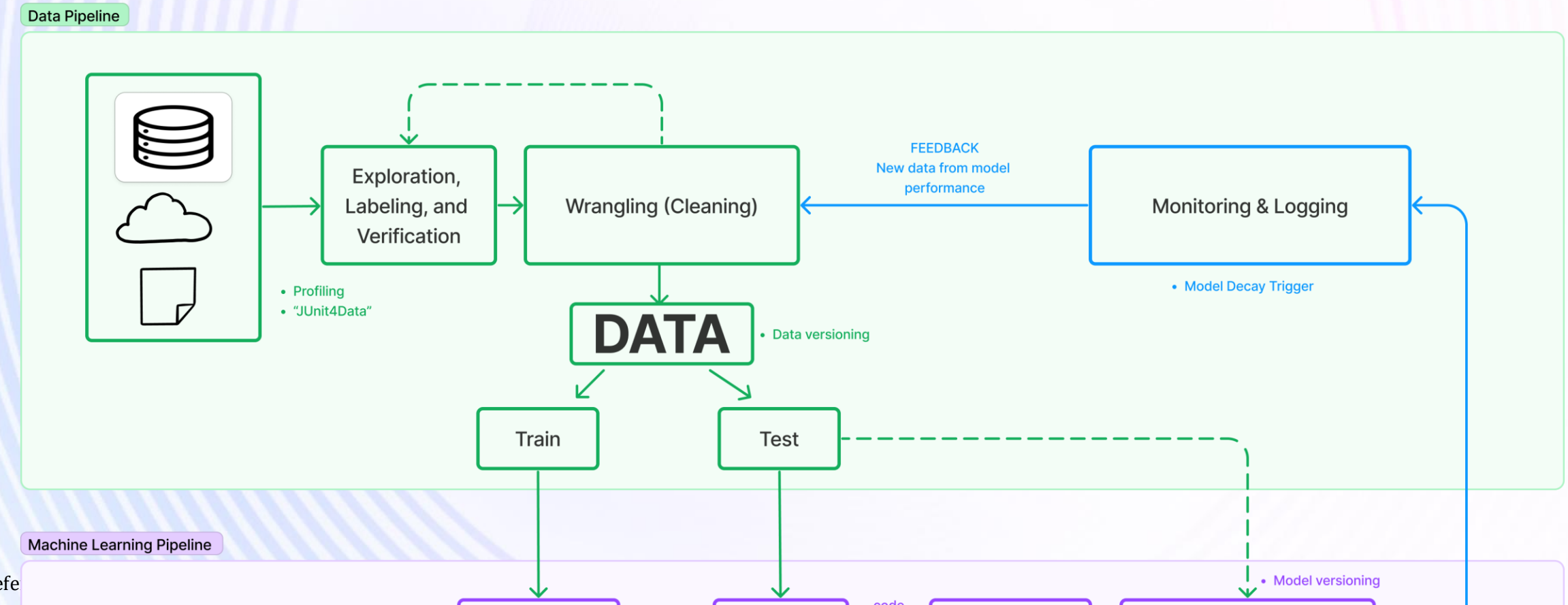
Interaction among Dev Ops, ML Ops, and Data Pipeline

ML Design Spec

- Input Data Analysis
- Pre-Processing Schema

ML Training Plan

- Groundtruth
- Data Splitting Schema
- Database Control
- Data Versioning Schema



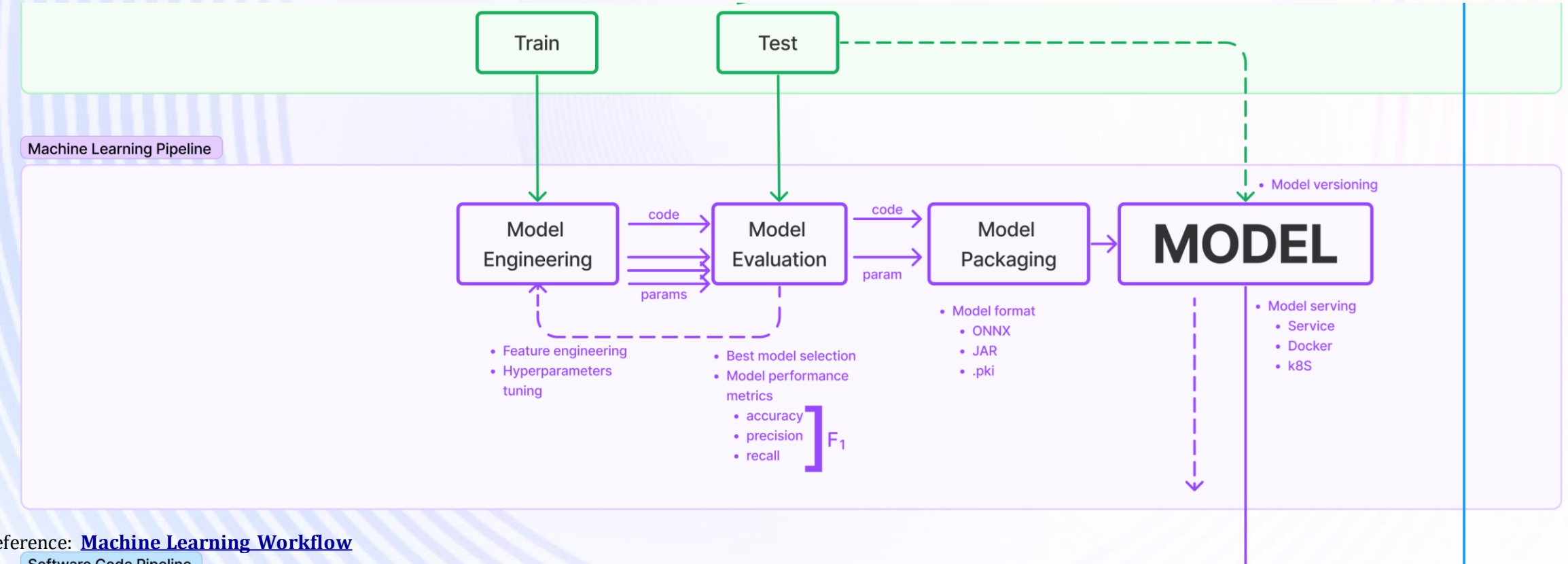
Interaction among Dev Ops, ML Ops, and Data Pipeline

ML Design Spec

- Modeling framework
- Data Augmentation
- Neural Network Architecture
- Tuning of Hyperparameters
- Final Model

ML Training Plan

- Groundtruth
- Data Splitting Schema
- Database Control
- Data Versioning Schema

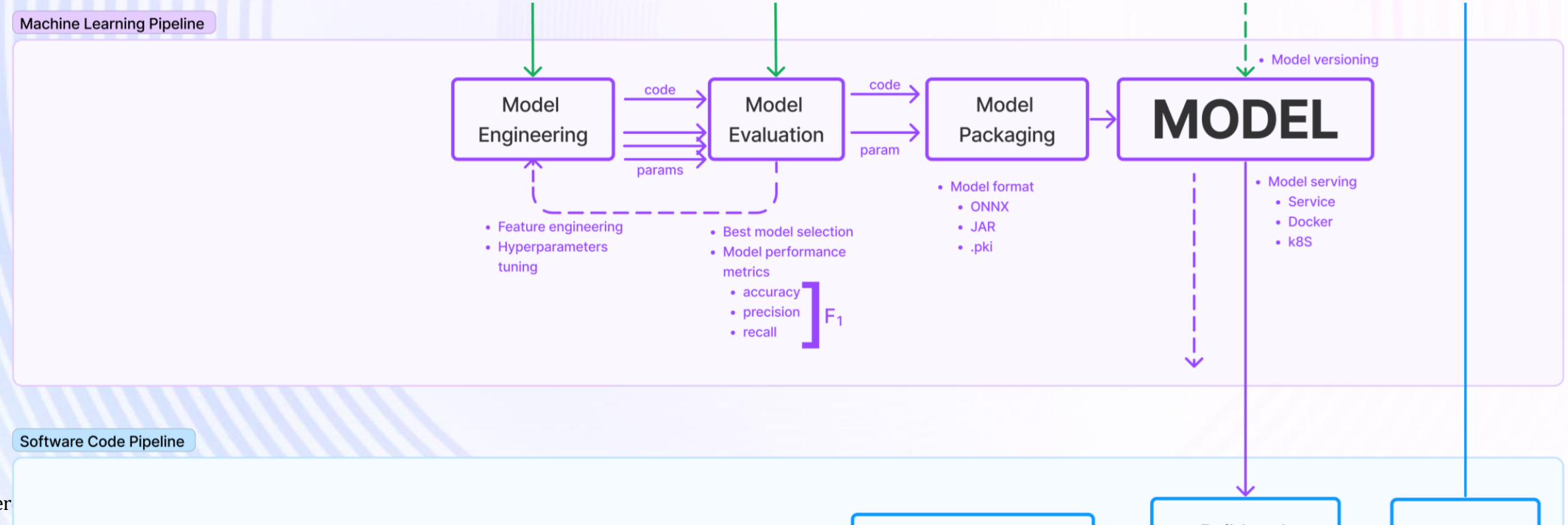


Reference: [Machine Learning Workflow]

Interaction among Dev Ops, ML Ops, and Data Pipeline

ML Validation Protocol/Report

- Study Design/Objectives
- Inclusion and Exclusion Criteria
- Study Endpoints and Performance Goals
- Statistical Considerations
- Model Results
  - Primary Endpoint (e.g., accuracy)
  - Subset Analysis – Cofounding Factors
- Groundtruth Evaluation



Refer

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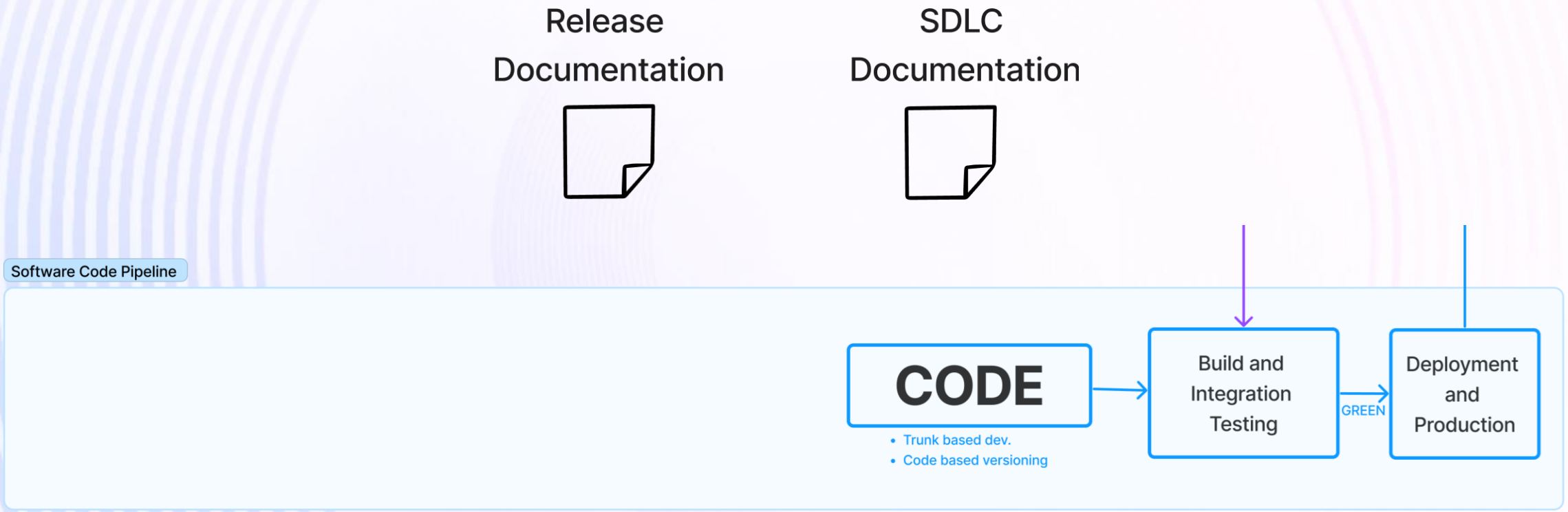

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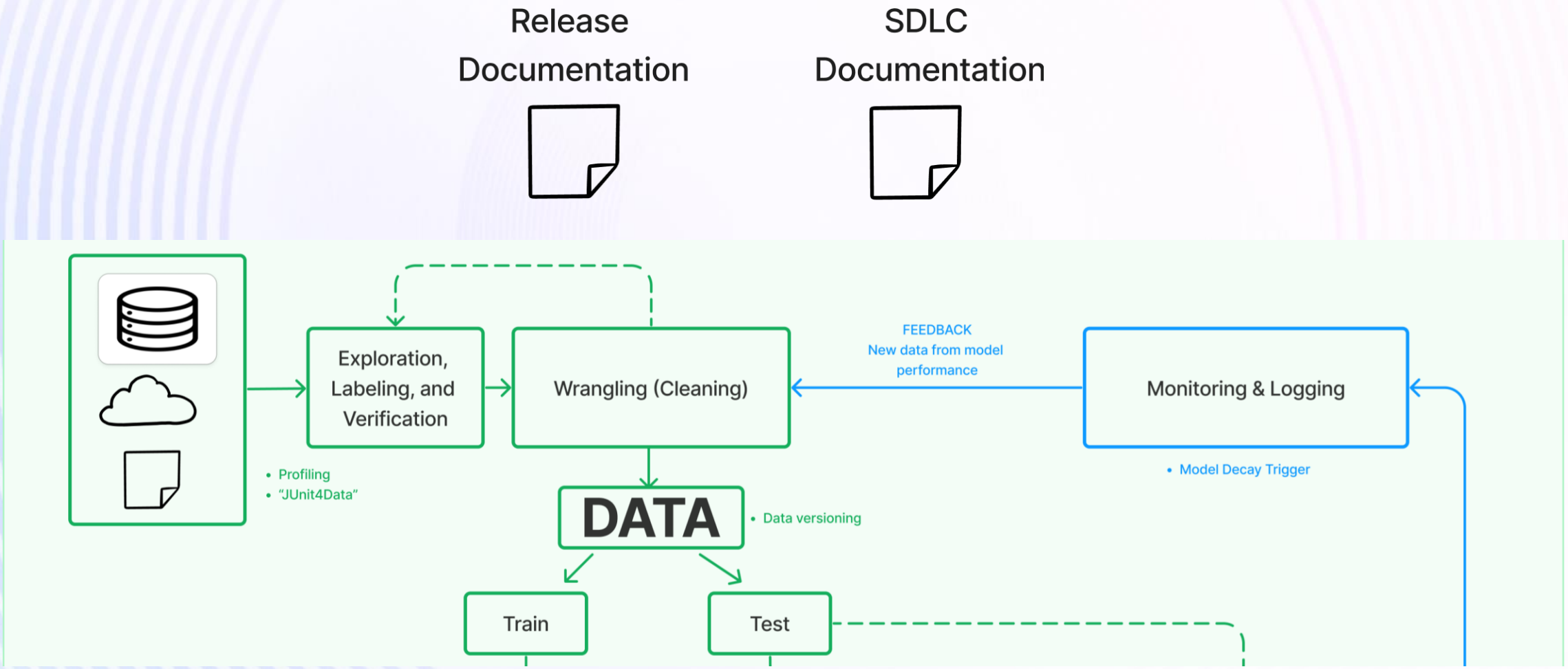
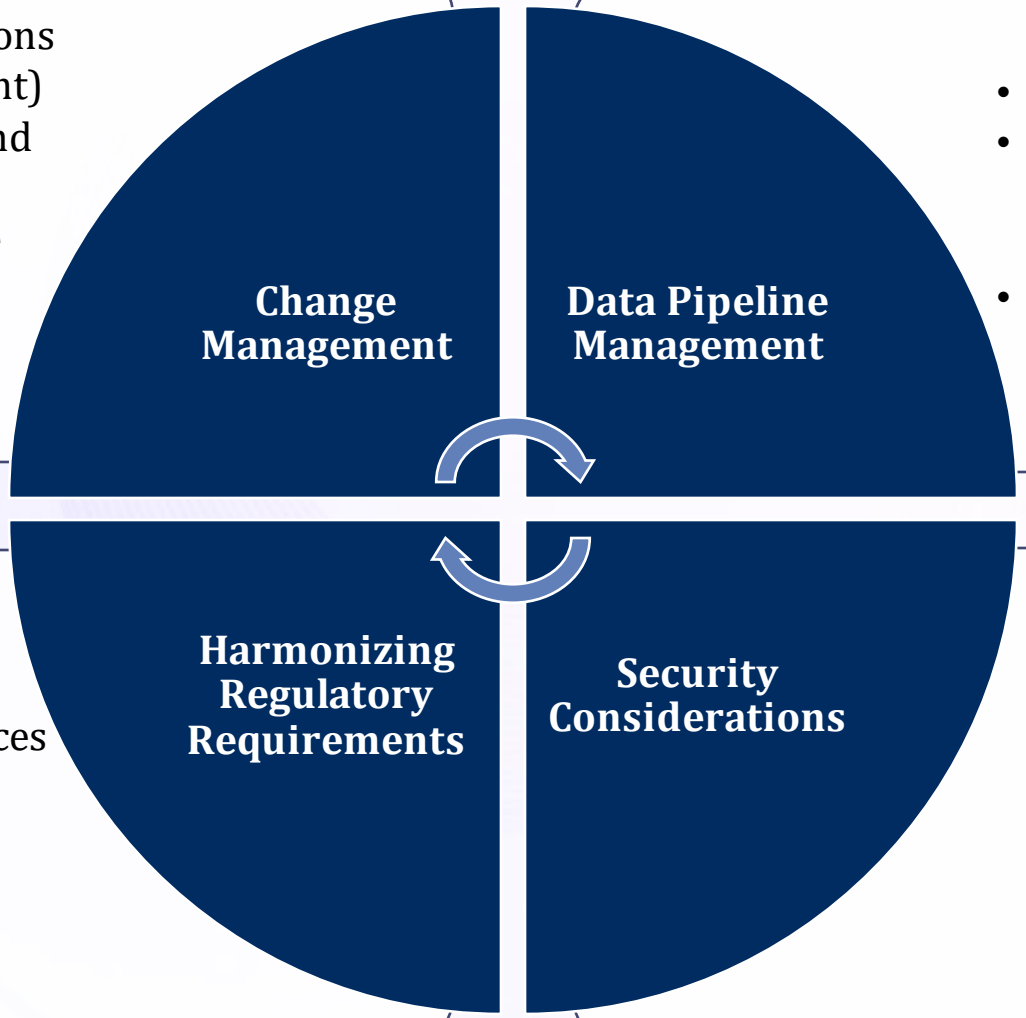


Reference: [Machine Learning Workflow]

Best Practices for Developing AI/ML Solutions

- Characterize device modifications (e.g., performance improvement)
- Method to develop, validate, and implement the changes
- Impact assessment to describe the risks and benefits and risk mitigations
- Labeling update



- Dataset splitting
- Representative (e.g., informed by clinical participants or deployed model performance)
- Manage the Risks of degradation, overfitting, unintended bias

- IMDRF SaMD WG
- ISO 13485
- Good Machine Learning Practices guiding principles
- IEC 62304 and IEC 82304
- IEC 34971
- EU AI Act
- ISO/IEC JTC 1/SC 42

- System-oriented attack
- Data-oriented attack
- Model-oriented attack

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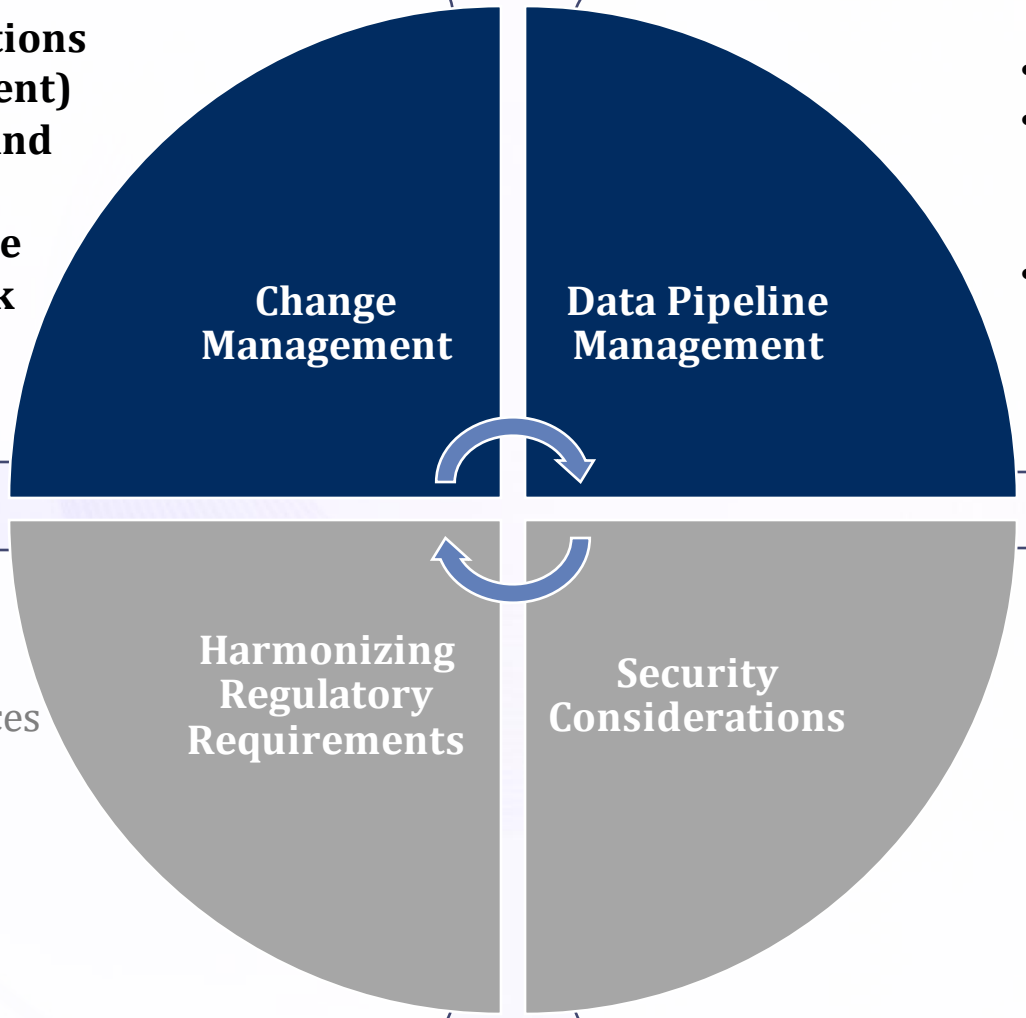

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Key Considerations for Conducting ML Training and Validation

Clinical Evaluation		
Valid Clinical Association	Analytical Validation	Clinical Validation
Is there a valid clinical association between your SaMD output and your SaMD's targeted clinical condition?	Does your SaMD correctly process input data to generate accurate, reliable and precise output data?	Does use of your SaMD's accurate, reliable and precise output data achieve your intended purpose in your target population in the context of clinical care?

- Relevance of available data to the clinical problem and current clinical practice;
- Data acquired in a consistent, clinically relevant and generalizable manner that aligns with the SaMD's intended use and modification plans;
- Appropriate separation between training, tuning, and test datasets; and
- Appropriate level of transparency (clarity) of the output and the algorithm aimed at users.

Reference: **US FDA AI and ML Discussion Paper**

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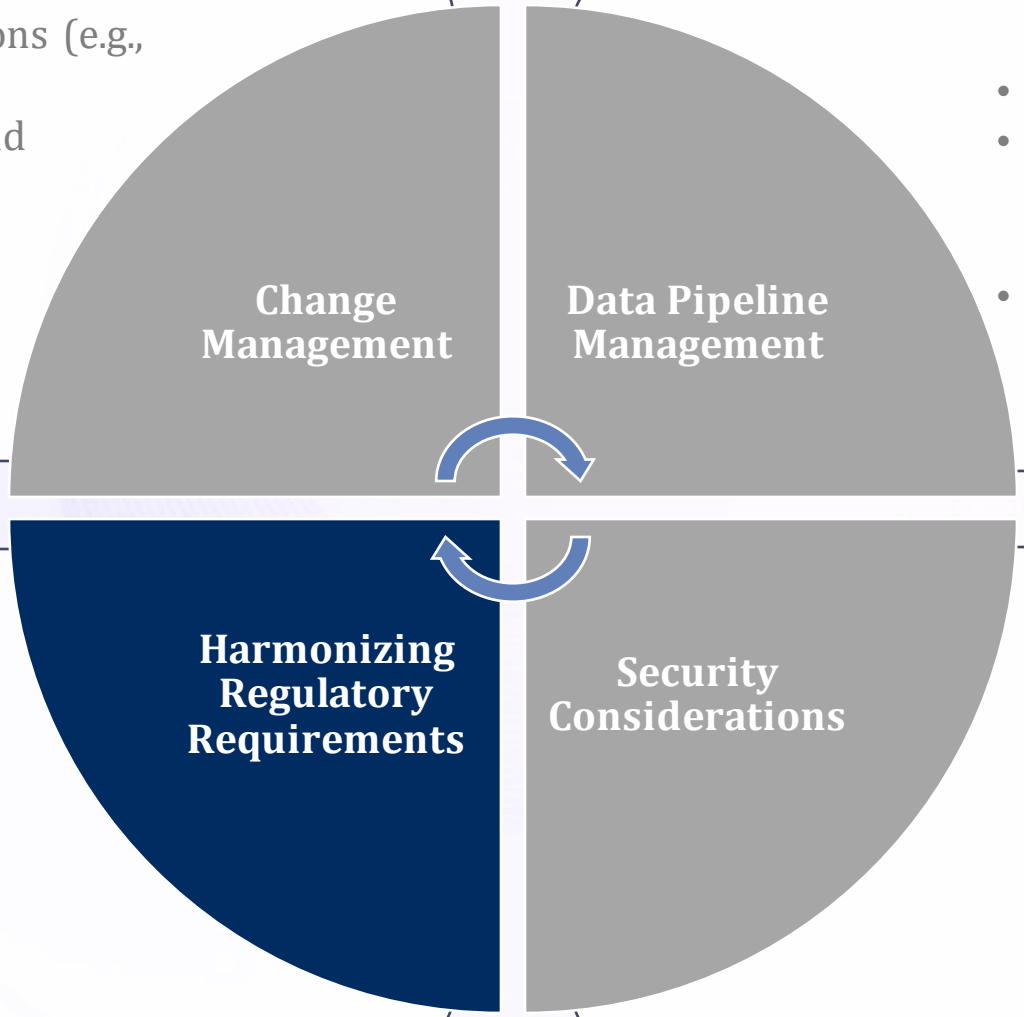

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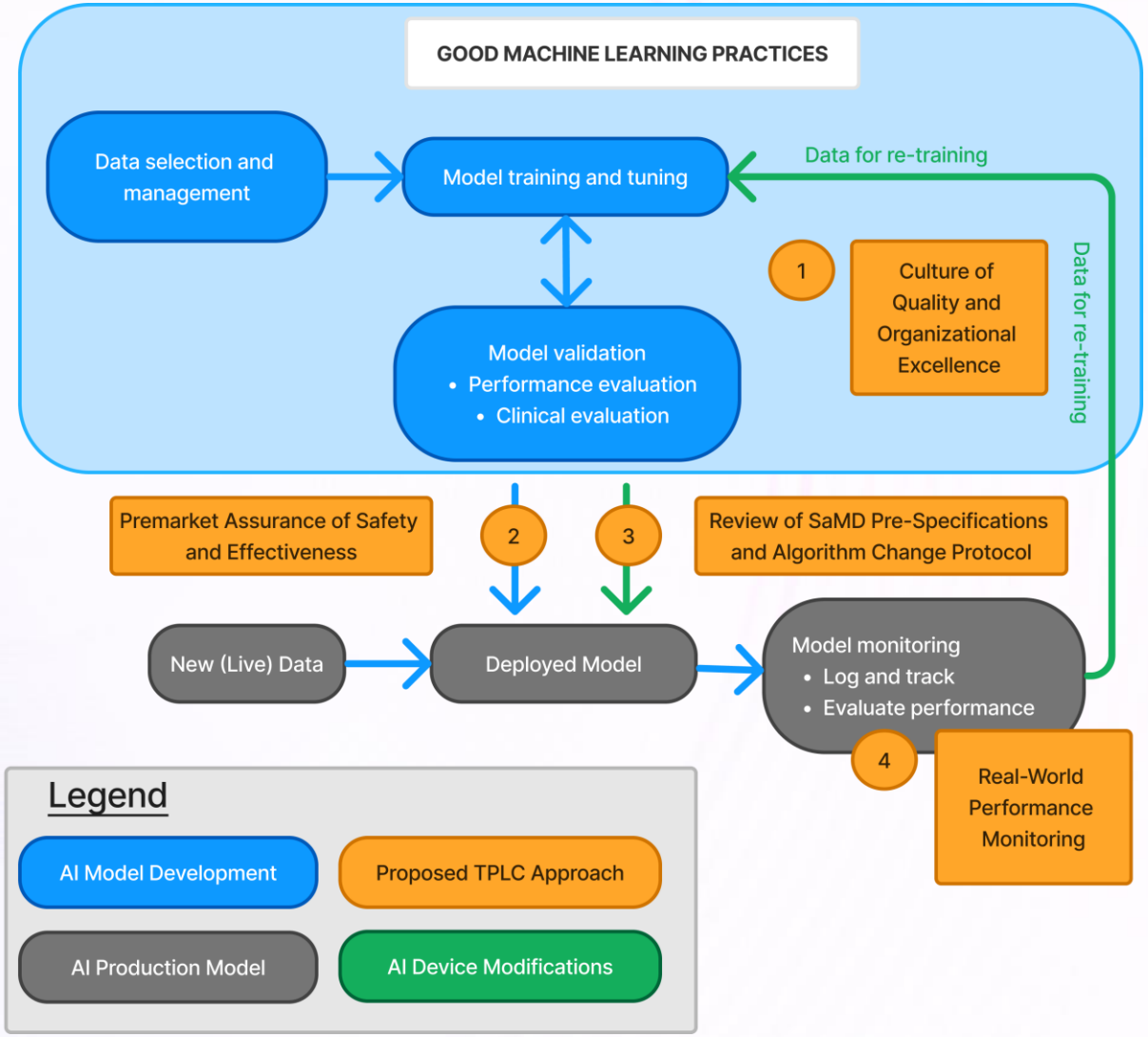
Good Machine Learning Practice (GMLP) Guiding Principles

Jointly identified by the FDA, Health Canada, MHRA [1.]

Key Principles in a Nutshell

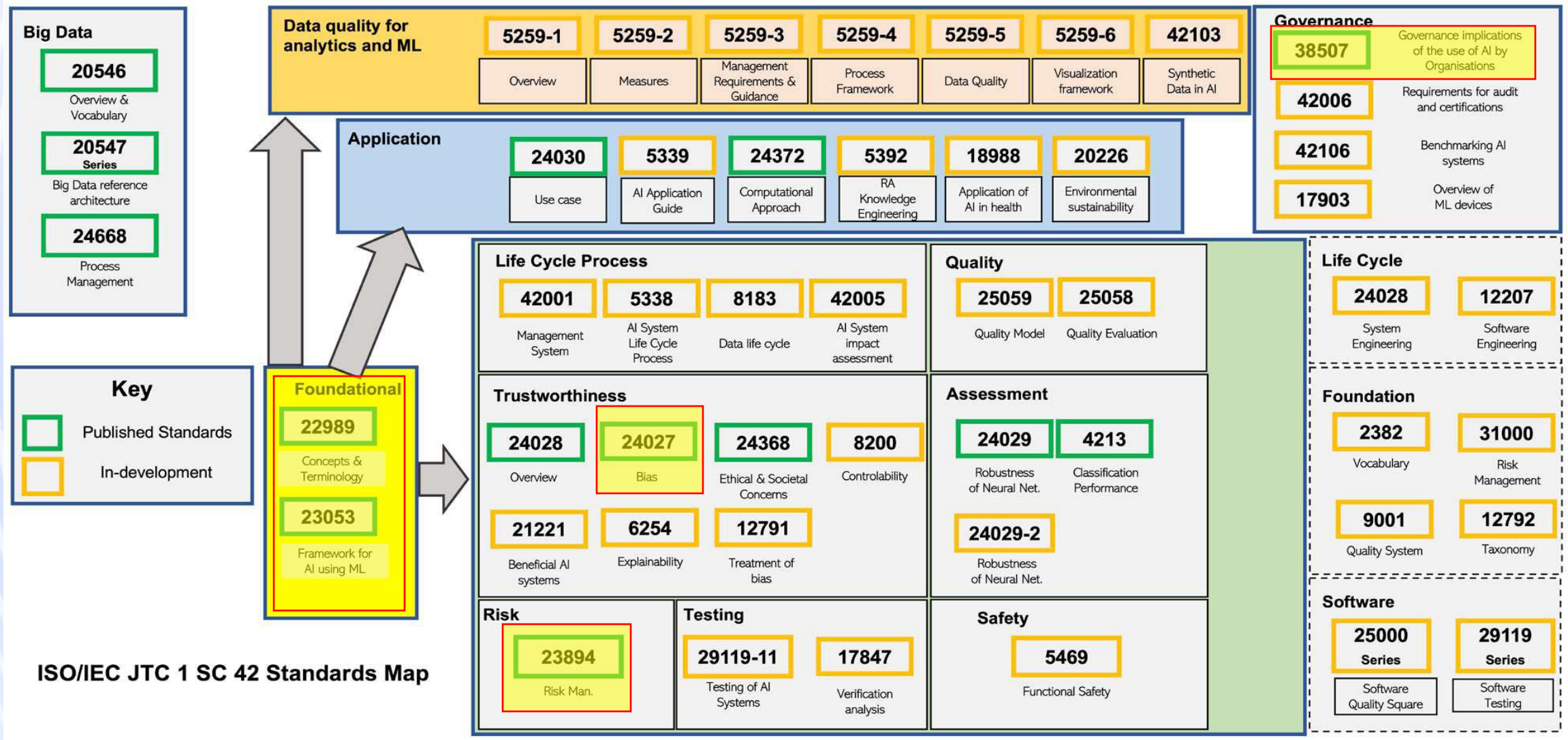
- **Good software engineering and security practices**
- **Dataset management (e.g., data split, ground truthing, generalizability…etc)**
- **Usability considerations (e.g., interpretability and explainability through validation, model labeling, product labeling…etc)**
- **Model monitoring and remediation (e.g., identify and address model degradation, unintended bias, overfitting…etc)**



Localized Regulation/Guidance

JURISDICTION	TITLE	CATEGORY
US FDA, Health Canada, MHRA	Good Machine Learning Practice for Medical Device Development: Guiding Principles	General – Medical Device
US FDA	Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions	Change Management
Japan PMDA	Regulatory Science on AI-based Medical Devices and Systems	General – Medical Device
Singapore HSA	Regulatory Guidelines for Software as Medical Device: A Life Cycle Approach (special section for AI	General – Medical Device
China NMPA	Review key points of Aided Decision-making Medical Device Software Using Deep Learning Techniques	General – Medical Device
South Korea MFDS	A guideline for Approval/Evaluation of Medical Device with Big Data and AI Technology	General – Medical Device
EU	General Data Protection Regulation (GDPR)	Data Privacy
EU	EU AI Act	General
EU	Cybersecurity Act	Security

ISO/IEC JTC 1/SC 42 Artificial Intelligence Committee



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Thank you!

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