Artificial intelligence in the diagnostic laboratory workflow

From innovation to regulation

KU LEUVEN

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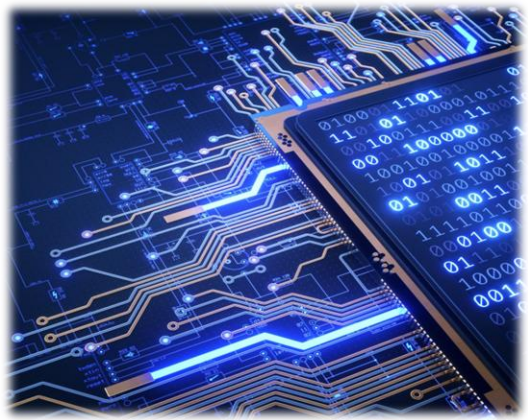
UZ LEUVEN

Laboratory Medicine

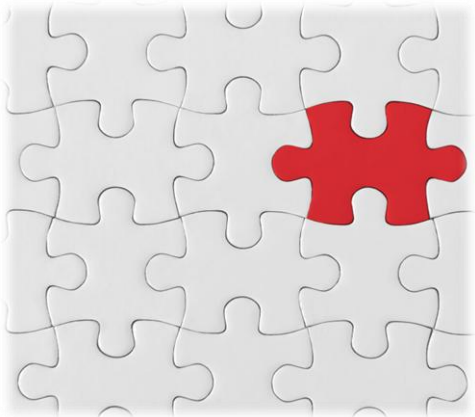
Key role of biomarkers in disease screening, diagnosis, prognosis, and patient monitoring.



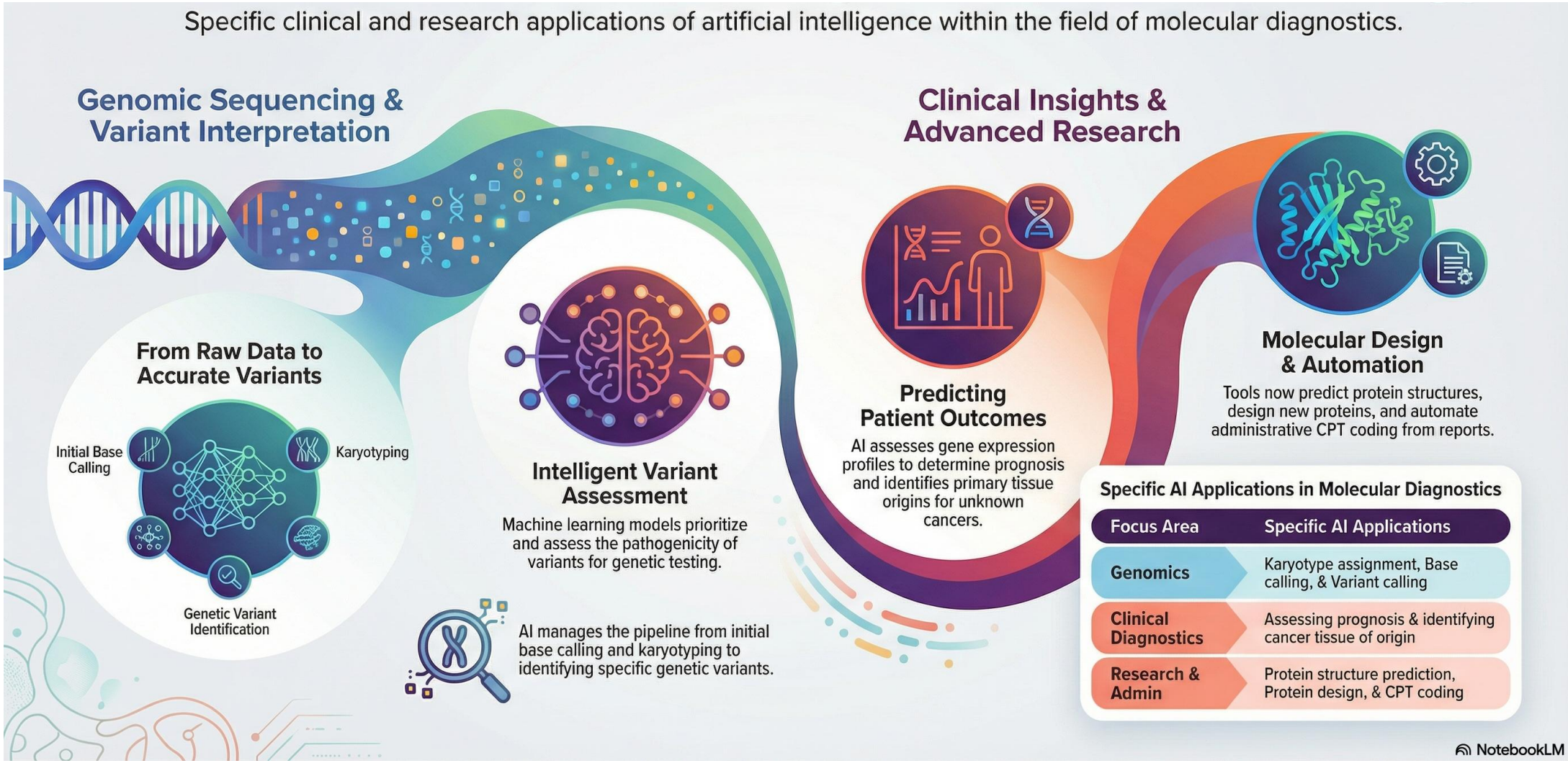
Artificial Intelligence (AI)

“Software that is good in pattern recognition”

Lieven Scheire

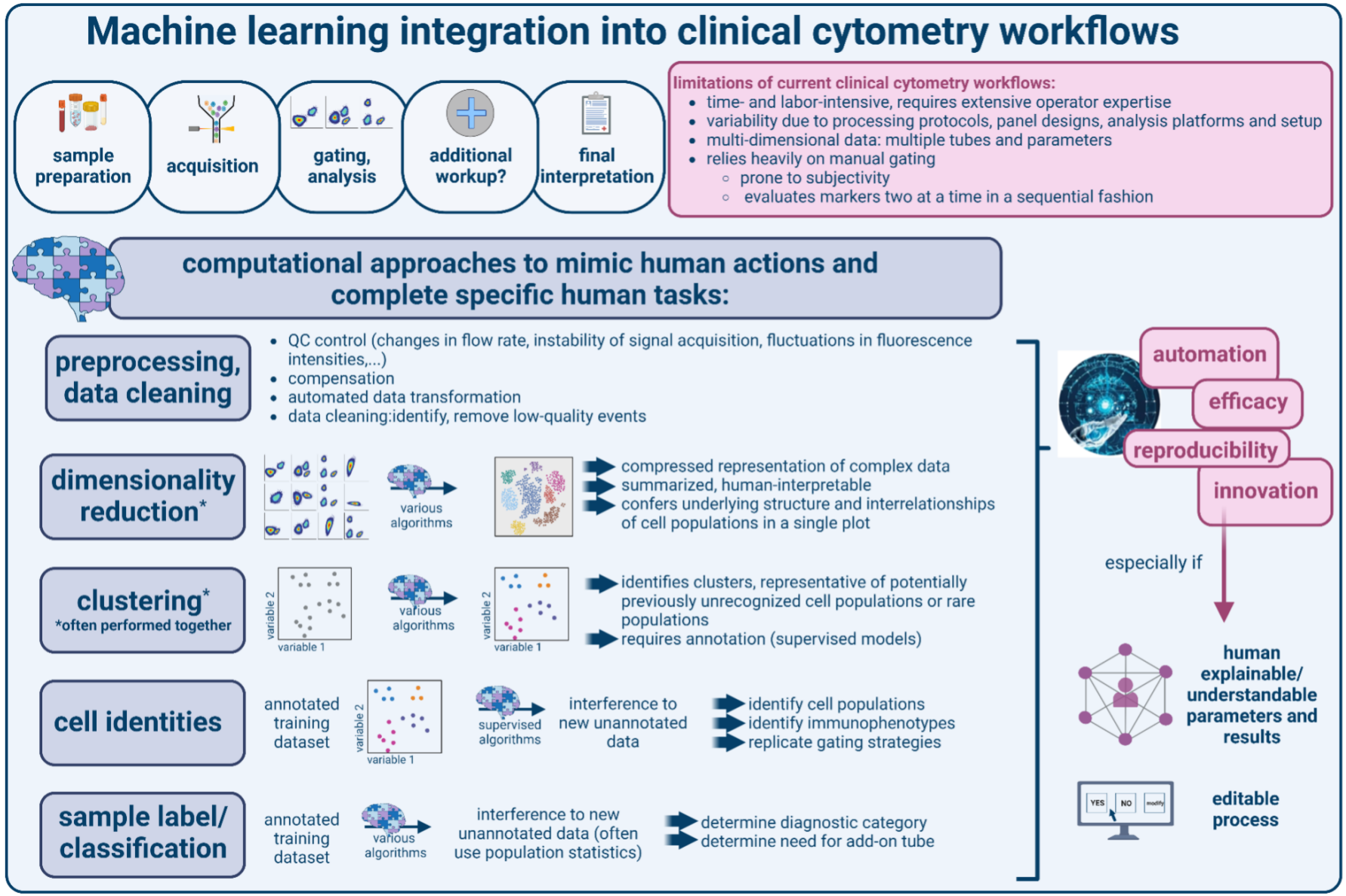


How to foster **innovation** in a regulated / accredited clinical laboratory environment?

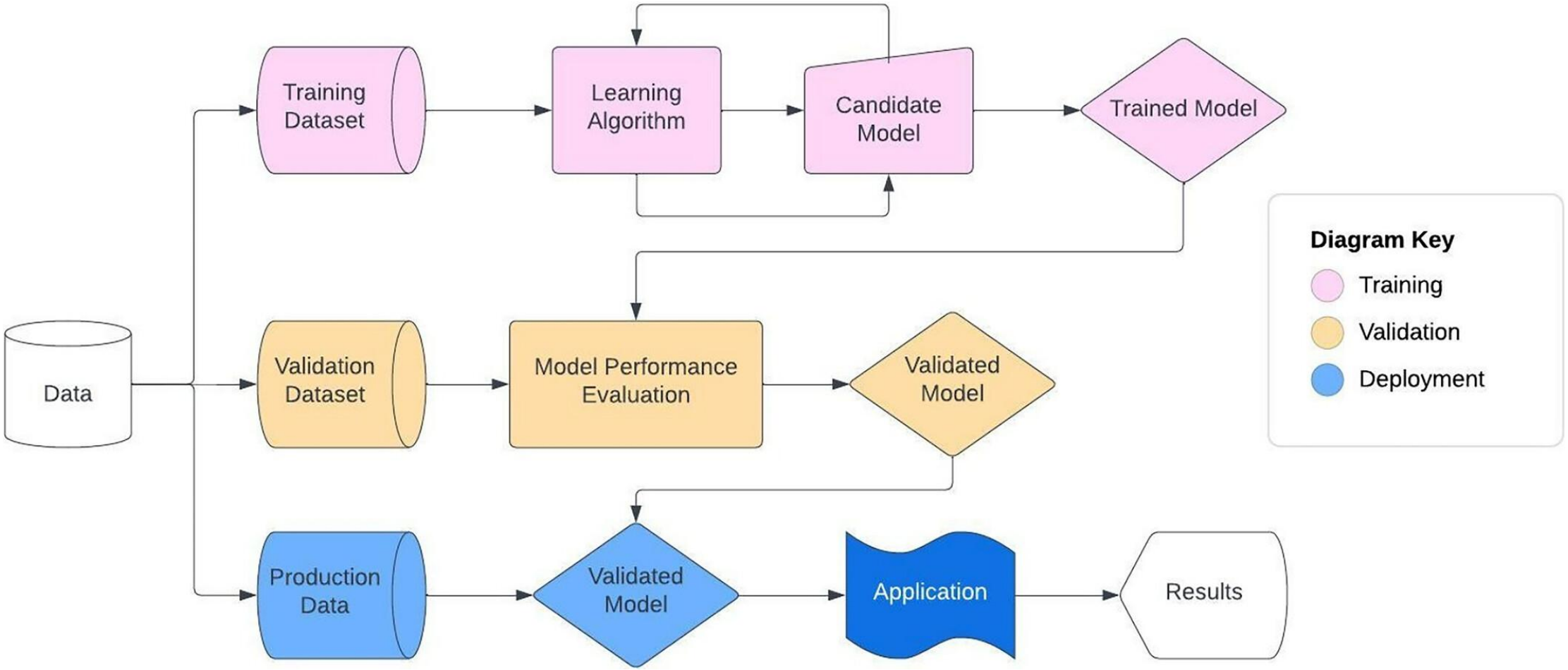


AI, artificial intelligence; CPT, Current Procedural Terminology.

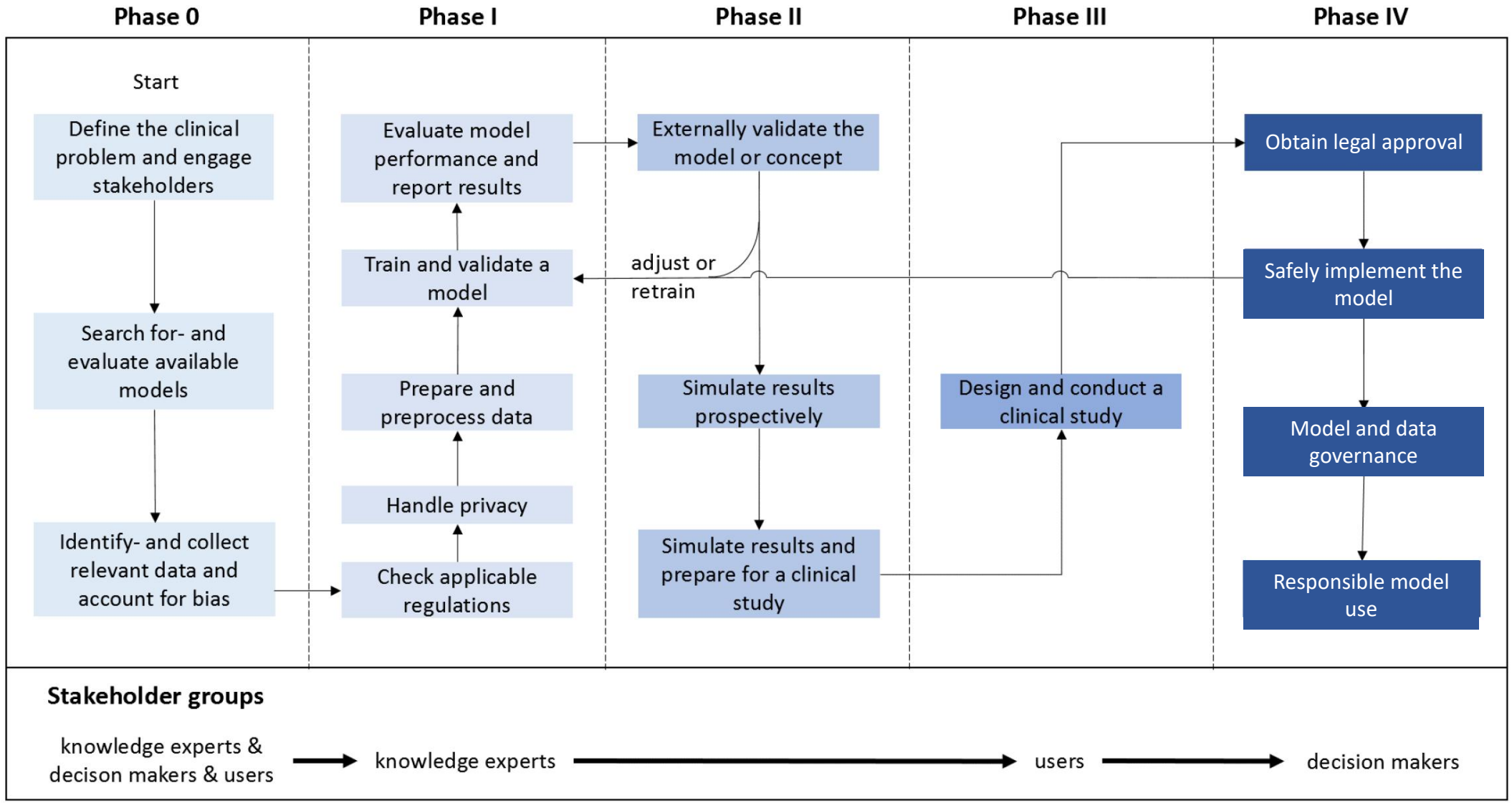
O'Leary, T. J, et al. J Mol Diagn. 2025, 27 (5), 323–335 - https://doi.org/10.1016/j.jmoldx.2025.01.005



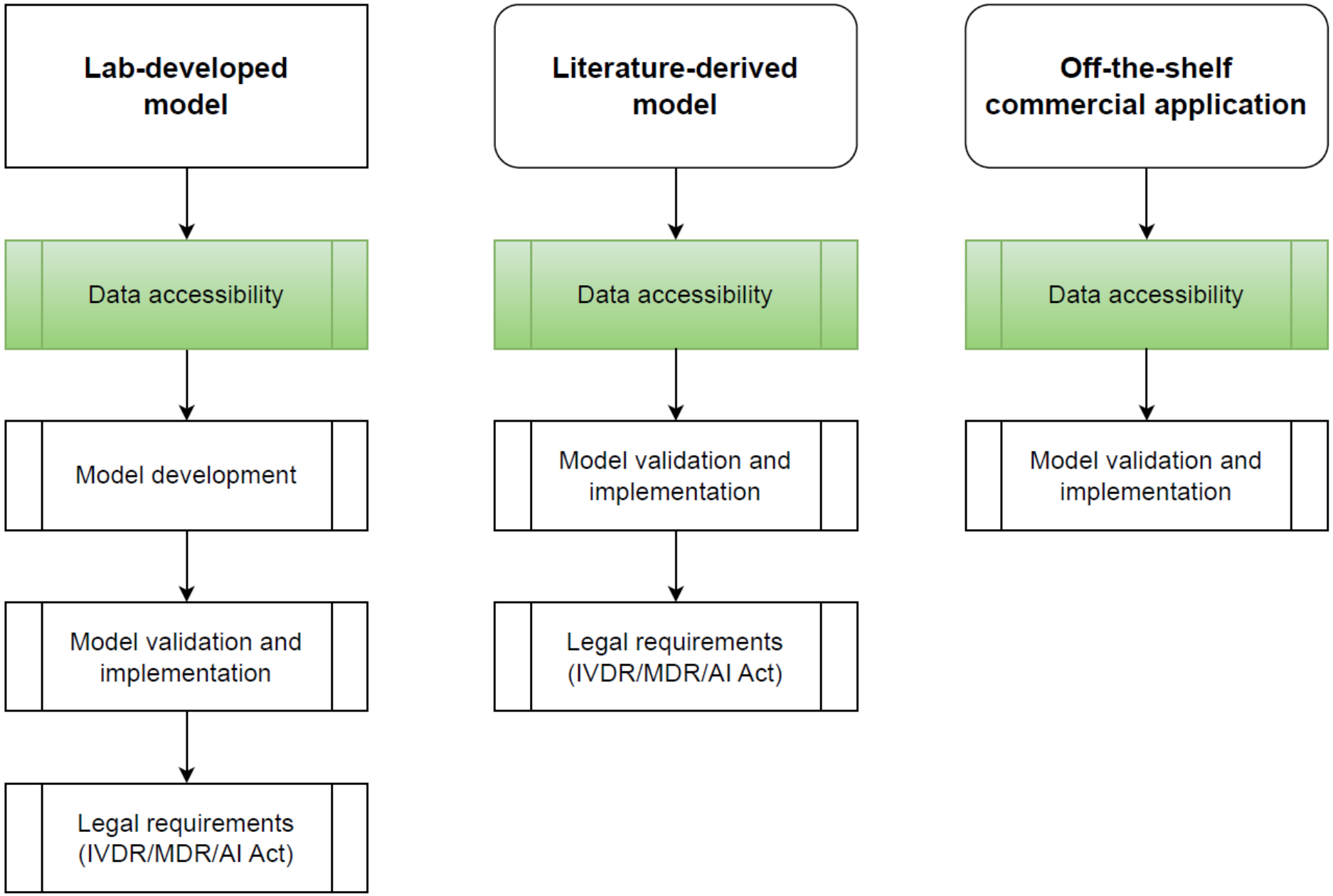
https://www.cap.org/member-resources/articles/is-it-magic-artificial-intelligence-integration-into-clinical-cytometry-workflows



Ng DP, et al. Cytometry Part B: Clinical Cytometry 2024, 106 (4), 228–238. - https://doi.org/10.1002/cyto.b.22166



Van De Sande D, et al. *BMJ Health Care Inform.* 2022;29(1):e100495.


Lab-developed model
Data accessibility
Model development
Model validation and implementation
Legal requirements (IVDR/MDR/AI Act)
Literature-derived model
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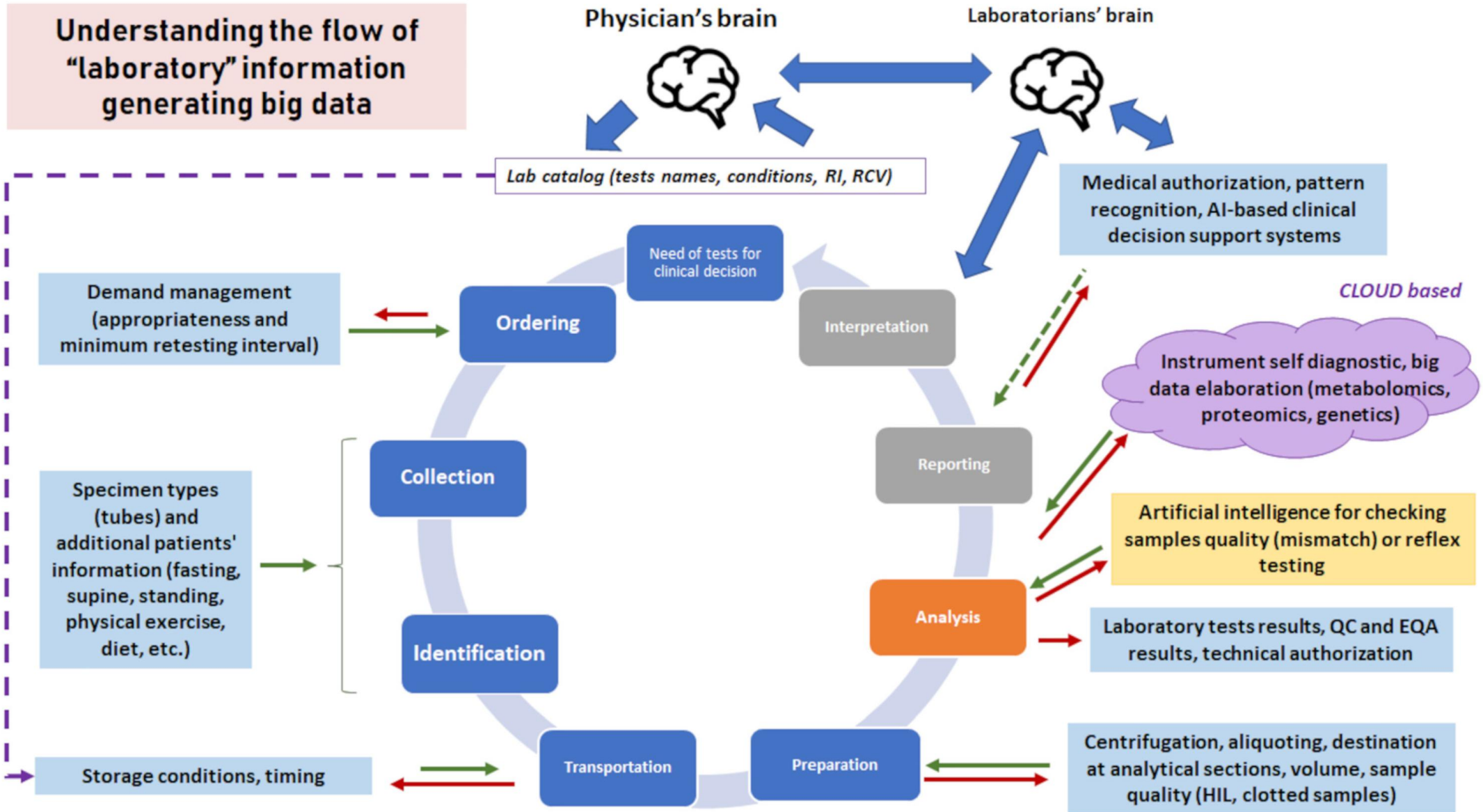
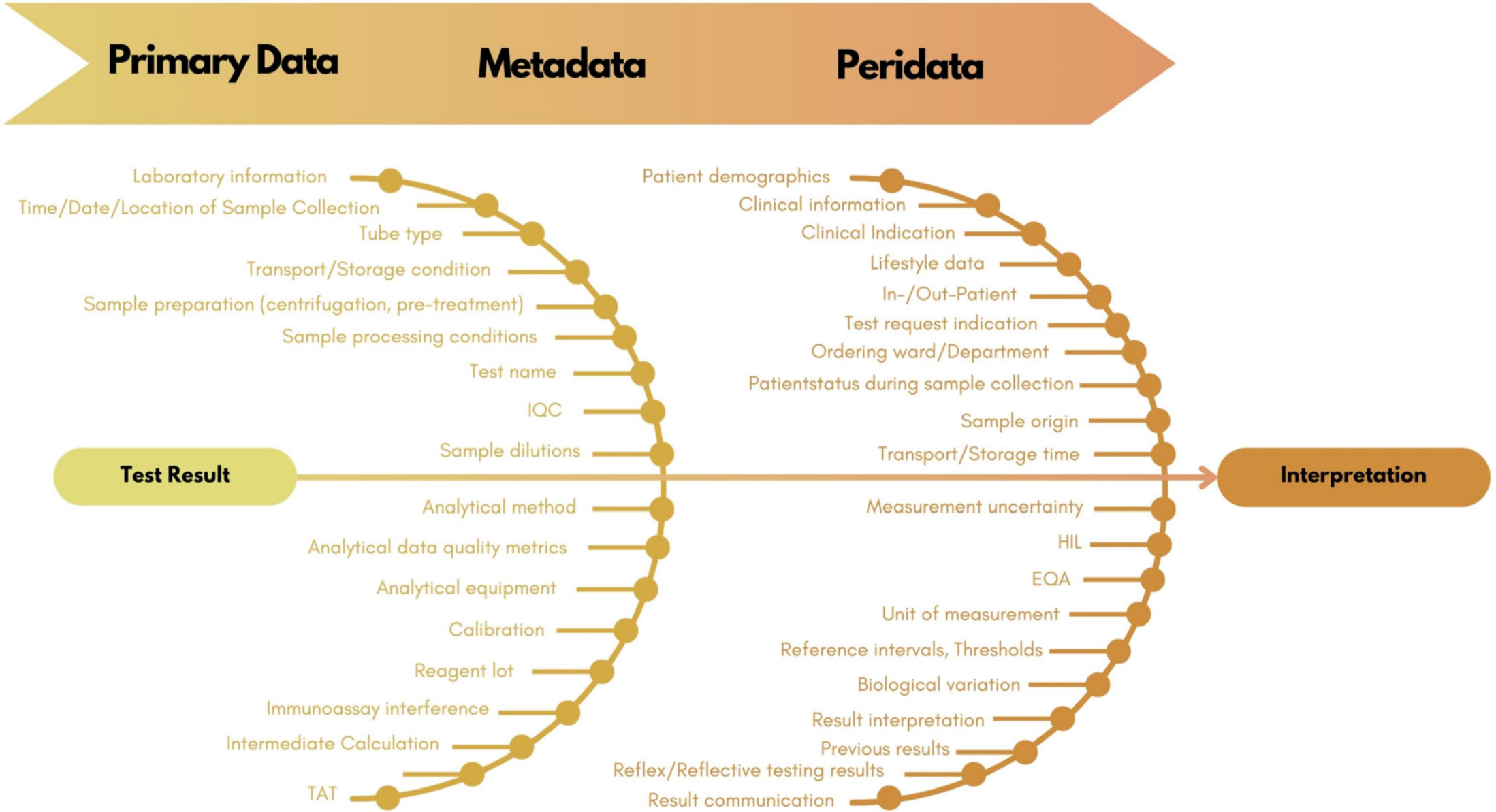


Padoan A, Plebani M. *Clin Chem Lab Med.* 2022;60(12):1875-80.



Padoan A, et al. *Clin Chem Lab Med.* 2025;63(4):684-91.

Primary data	Laboratory test results
Metadata	Data derived from the testing process that describe the characteristics and the requirements that are relevant for assessing the quality and the validity of laboratory test results.
Peridata	Data derived from the testing process that are relevant for the interpretation of the results within the clinical context, making that data actionable for the patients' care.

Padoan A, et al. *Clin Chem Lab Med.* 2025;63(4):684-91.

SNOMED CT

The global language of healthcare

LOINC®

Belgische subset LOINC

ICD-11

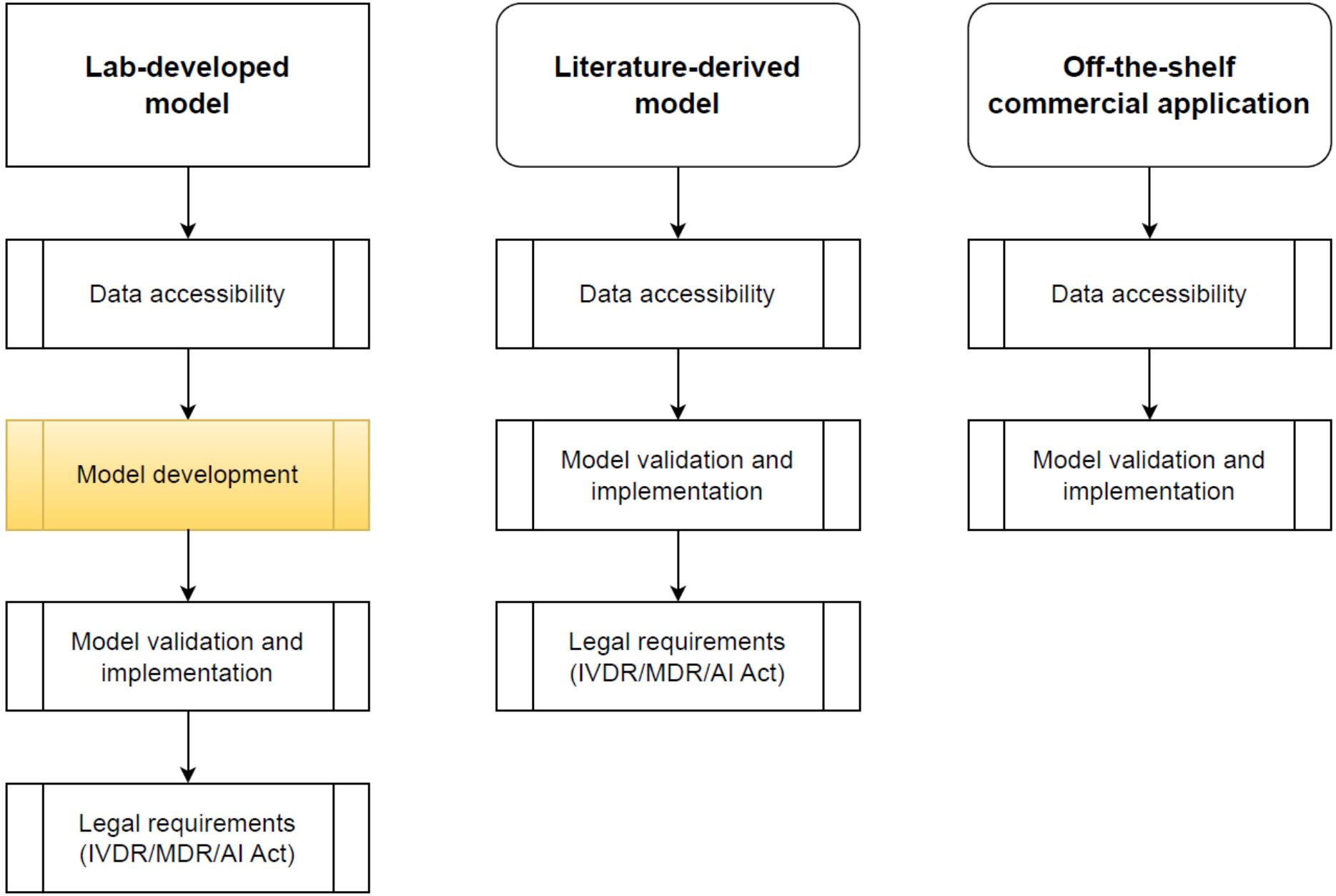
International Classification of Diseases 11th Revision

The global standard for diagnostic health information

DATA STANDARDS

OMOP Common Data Model

The Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM) is an open community data standard, designed to standardize the structure and content of observational data and to enable efficient analyses that can produce reliable evidence.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Clinical Chemistry 69:7
690–698 (2023)

Special Report

Machine Learning in Laboratory Medicine: Recommendations of the IFCC Working Group

Stephen R. Master [a,b,*] Tony C. Badrick,[c] Andreas Bietenbeck [d] and Shannon Haymond[e,f,*]

Table 1. Summary of considerations for determining when to use machine learning.

When NOT to use machine learning	When to use machine learning
1. New cases not similar enough to any of the training examples—failure to generalize	1. Rules cannot be coded
2. Similar inputs associated with different outputs	2. Throughput can be improved with automation
3. Defined outcomes are controversial because of an ill-defined gold standard	3. One cannot perceive differences by eye (handcrafted features)
4. Insufficient infrastructure or resources (data scientists) for machine learning	4. Narrowly derived problem
5. Unreliable outcome labelling, lack of in-house expertise to provide training diagnoses.	5. Prediction is high-volume and repetitive
6. No clear strategy or understanding of the operational context	
7. Traditional rule-based software methods are equivalent/better (simple or well-characterized problem)	
8. Insufficient data (quantity or quality)	

PROBAST+AI: an updated quality, risk of bias, and applicability assessment tool for prediction models using regression or artificial intelligence methods

Karel G M Moons,[1] Johanna A A Damen,[1,2] Tabea Kaul,[1] Lotty Hooft,[1,2]...

thebmj | *BMJ* 2025;388:e082505 | doi: 10.1136/bmj-2024-082505

TRIPOD+AI statement: updated guidance for reporting clinical prediction models that use regression or machine learning methods

Gary S Collins,[1] Karel G M Moons,[2] Paula Dhiman,[1] Richard D Riley,[3,4] Andrew L Beam,[5]...

thebmj | *BMJ* 2024;385:e078378 | doi: 10.1136/bmj-2023-078378

The IJMEDI checklist for assessment of medical AI

Requirement	Authors			Reviewers		
	NA	No	Yes	OK	mR	MR
Problem Understanding						
1. Is the study population described, also in terms of inclusion/exclusion criteria (e.g., patients older than 18 tested for COVID-19; all inpatients hospitalized for 24 or more hours)? §	○	○	○	○	○	○
2. Is the study design described? (e.g., retrospective, prospective, cross-sectional [1], observational, randomized control trial [2]) §	○	○	○	○	○	○
...						

ChAMAI

Cabitza F., Campagner, A. *Int. J. Med. Inform*. 2021

Users / stakeholders

- ✓ Academic institutions
- ✓ Researchers
- ✓ Healthcare professionals
- ✓ Journals

Not adapted for laboratory medicine !

PROBAST+AI: an updated quality, risk of bias, and applicability assessment tool for prediction models using regression or artificial intelligence methods

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ChAMAI

Cabitza F., Campagner, A. *Int. J. Med. Inform*. 2021

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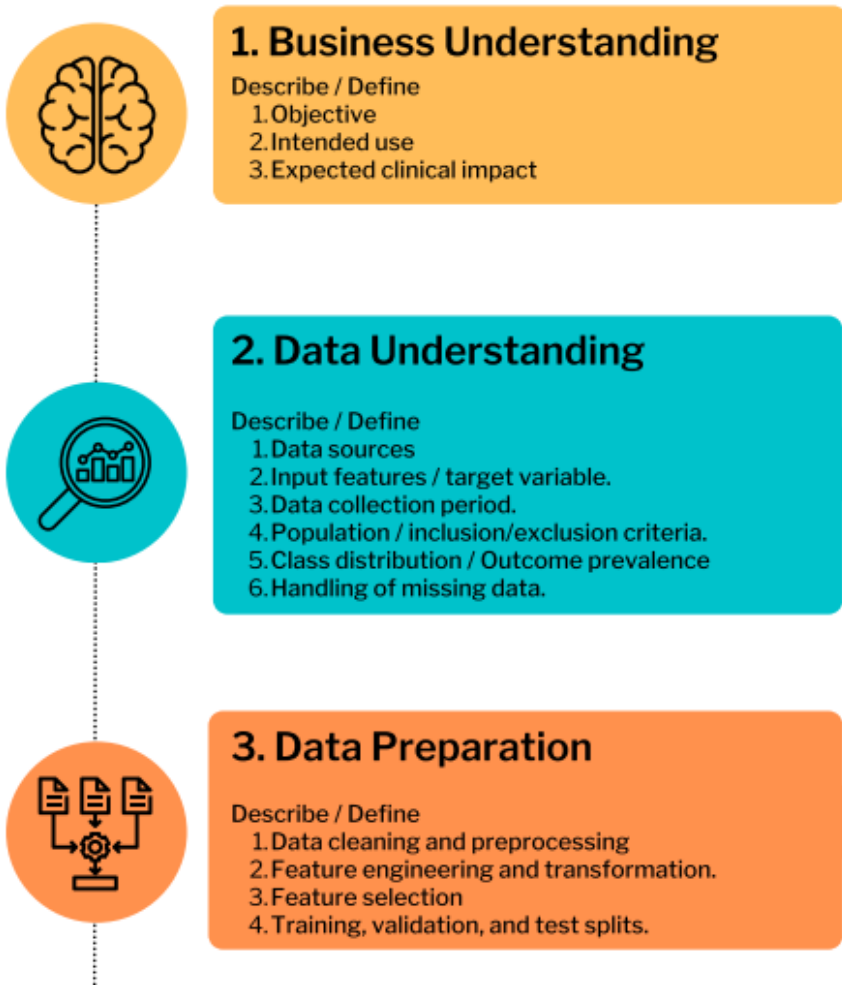
Not adapted for laboratory medicine !

ChAMAI

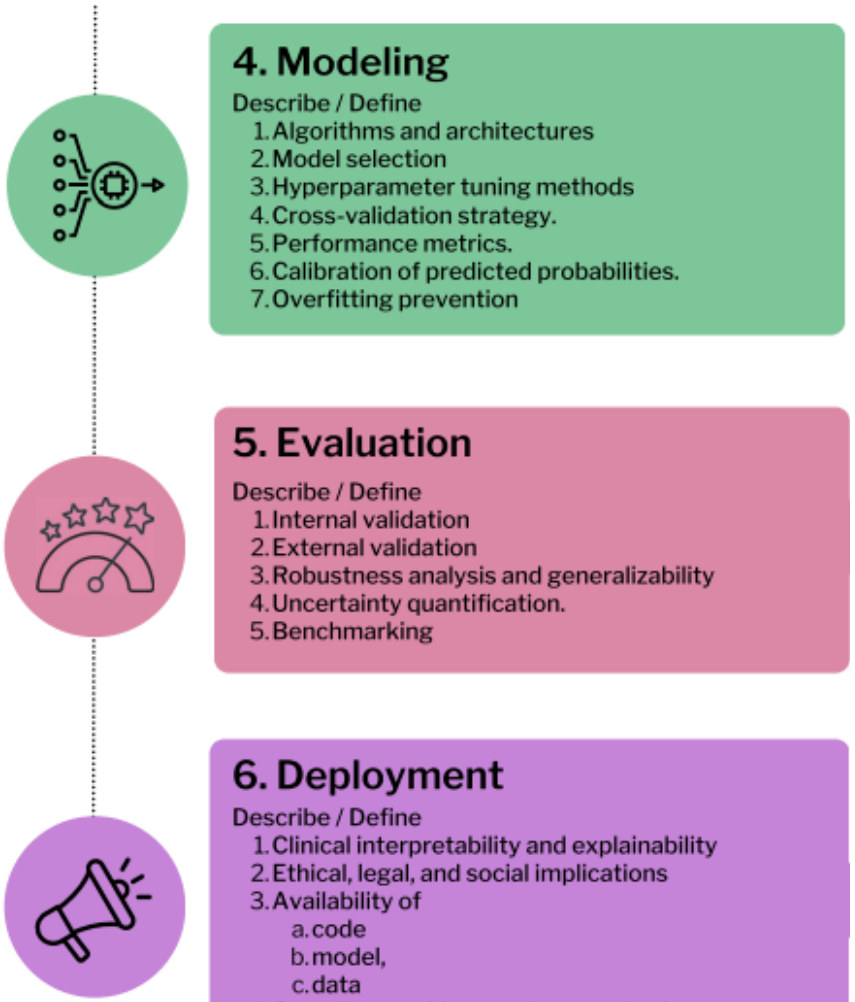
EFLM



Carobene A, et al. Clin Chem Lab Med (CCLM). 2025;64(1):27-40.

ChAMAI

EFLM



4. Modeling

Describe / Define

1. Algorithms and architectures
2. Model selection
3. Hyperparameter tuning methods
4. Cross-validation strategy.
5. Performance metrics.
6. Calibration of predicted probabilities.
7. Overfitting prevention

5. Evaluation

Describe / Define

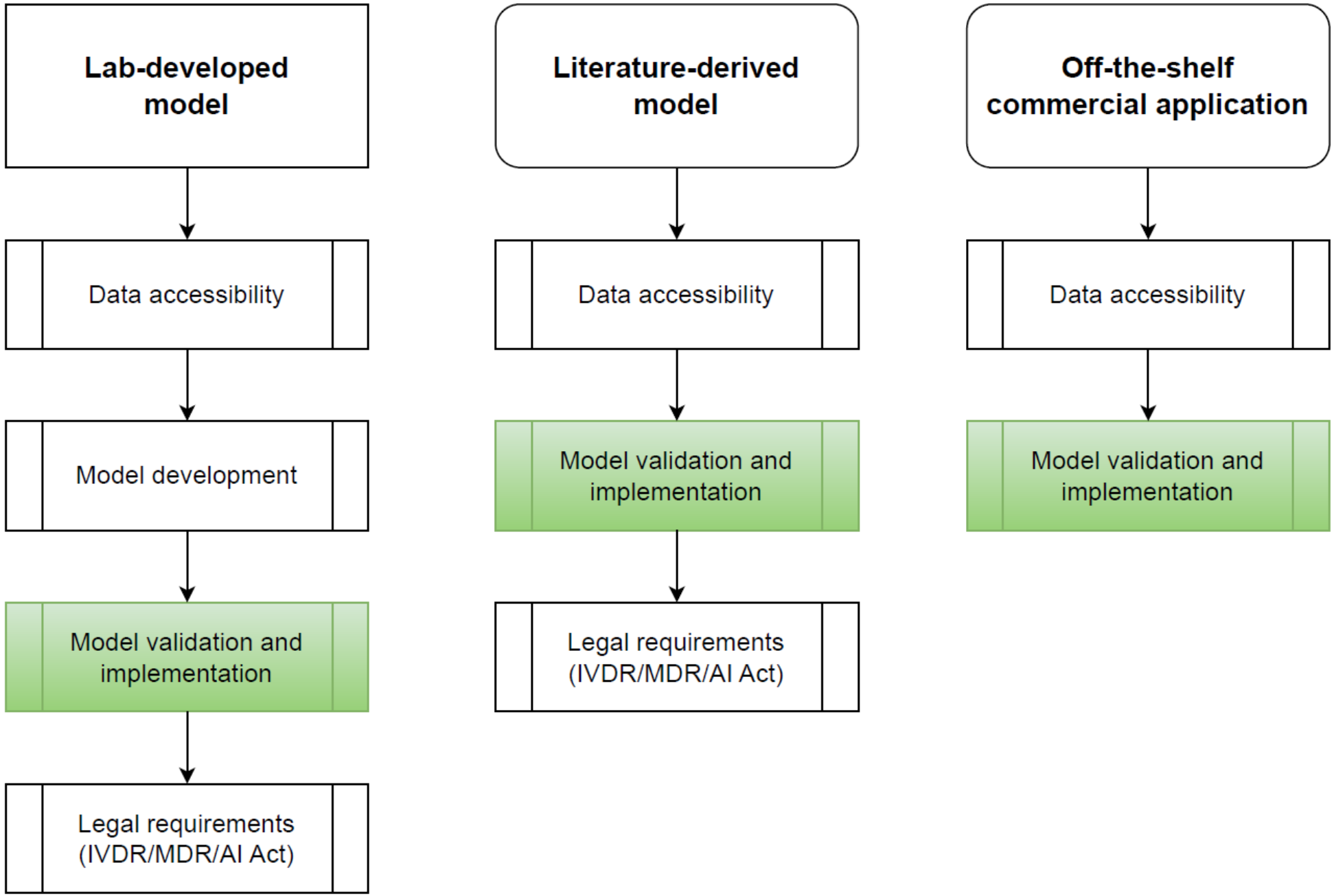
1. Internal validation
2. External validation
3. Robustness analysis and generalizability
4. Uncertainty quantification.
5. Benchmarking

6. Deployment

Describe / Define

1. Clinical interpretability and explainability
2. Ethical, legal, and social implications
3. Availability of
    a. code
    b. model,
    c. data
4. Compliance with reporting standards
5. Monitoring and updating the model

Carobene A, et al. Clin Chem Lab Med (CCLM). 2025;64(1):27-40.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ISO/DIS 24051-1

Medical laboratories

Part 1: General principles for the application of artificial intelligence in medical laboratories

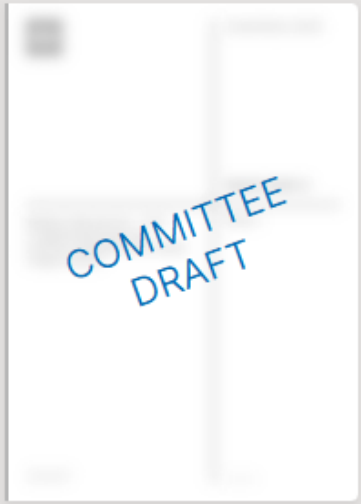
Under development

This Draft International Standard is in the enquiry phase with ISO members.

Abstract

This document specifies general principles for the application of artificial intelligence in the medical laboratory. This document is applicable to methods commonly considered subsets of artificial intelligence, including fuzzy logic, Bayesian networks, supervised and unsupervised machine learning, deep learning, neural networks, expert systems, robotics, natural language processing and image analysis.

https://www.iso.org/standard/87673.html



ISO/CD 24051-2

Medical laboratories

Part 2: Digital pathology and artificial intelligence (AI)-based image analysis

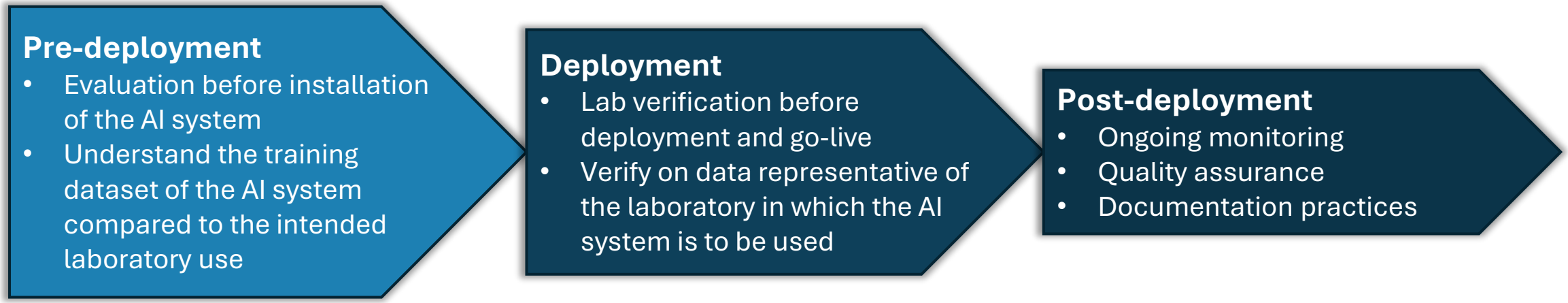
Under development

A draft is being reviewed by the committee.

Abstract

This document specifies requirements and gives recommendations for the digitalization of slide-mounted, stained sections, processing of digital whole slide images, and artificial intelligence (AI) based image analysis to support anatomical pathology examination. This document focuses on sections from formalin-fixed paraffin-embedded (FFPE) tissues (derived e.g. from surgical resection, biopsy or autopsy). It is also applicable to paraffin-embedded tissue fixed by fixatives other than formalin. This document is applicable to in vitro diagnostic examinations using digital pathology and AI-based image analysis performed by medical laboratories, in particular but not limited to anatomical pathology laboratories. It is also intended to be used by health institutions, in vitro diagnostics developers and manufacturers, and regulatory authorities. NOTE International, national or regional regulations or requirements can also apply to specific topics covered in this document.

https://www.iso.org/standard/87674.html



https://www.iso.org/standard/87673.html (ISO 24051-1, figure based on CD2 final draft)

Model Facts

Model name: Deep Sepsis

Locale: Duke University Hospital

Approval Date: 09/22/2019

Last Update: 01/13/2020

Version: 1.0

Summary

This model uses EHR input data collected from a patient's current inpatient encounter to estimate the probability that the patient will meet sepsis criteria within the next 4 hours. It was developed in 2016-2019 by the Duke Institute for Health Innovation. The model was licensed to Cohere Med in July 2019.

Mechanism

- **Outcome** ..... sepsis within the next 4 hours, see outcome definition in "Other Information"
- **Output** ..... 0% - 100% probability of sepsis occurring in the next 4 hours
- **Target population** ..... all adult patients >18 y.o. presenting to DUH ED
- **Time of prediction** ..... every hour of a patient's encounter
- **Input data source** ..... electronic health record (EHR)
- **Input data type** ..... demographics, analytes, vitals, medication administrations
- **Training data location and time-period** ..... DUH, diagnostic cohort, 10/2014 – 12/2015
- **Model type** ..... Recurrent Neural Network

Validation and performance

	Prevalence	AUC	PPV @ Sensitivity of 60%	Sensitivity @ PPV of 20%	Cohort Type	Cohort URL / DOI
Local Retrospective	18.9%	0.88	0.14	0.50	Diagnostic	arxiv.org/abs/1708.05894
Local Temporal	6.4%	0.94	0.20	0.66	Diagnostic	jmir.org/preprint/15182
Local Prospective	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
External	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Target Population	6.4%	0.94	0.20	0.66	Diagnostic	jmir.org/preprint/15182

Uses and directions

- **Benefits:** Early identification and prompt treatment of sepsis can improve patient morbidity and mortality.
- **Target population and use case:** Every hour, data is pulled from the EHR to calculate risk of sepsis for every patient at the DUH ED. A rapid response team nurse reviews every high-risk patient with a physician in the ED to confirm whether or not to initiate treatment for sepsis.
- **General use:** This model is intended to be used to by clinicians to identify patients for further assessment for sepsis. The model is not a diagnostic for sepsis and is not meant to guide or drive clinical care. This model is intended to complement other pieces of patient information related to sepsis as well as a physical evaluation to determine the need for sepsis treatment.
- **Appropriate decision support:** The model identifies patient X as at a high risk of sepsis. A rapid response team nurse discusses the patient with the ED physician caring for the patient and they agree the patient does not require treatment for sepsis.
- **Before using this model:** Test the model retrospectively and prospectively on a diagnostic cohort that reflects the target population that the model will be used upon to confirm validity of the model within a local setting.
- **Safety and efficacy evaluation:** Analysis of data from clinical trial (NCT03655626) is underway. Preliminary data shows rapid response team, nurse-driven workflow was effective at improving sepsis treatment bundle compliance.

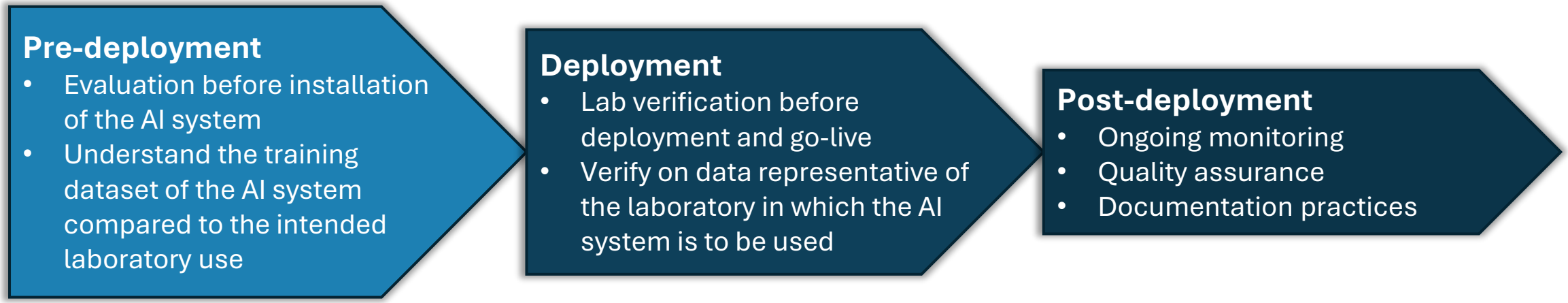
Warnings

- **Risks:** Even if used appropriately, clinicians using this model can misdiagnose sepsis. Delays in a sepsis diagnosis can lead to morbidity and mortality. Patients who are incorrectly treated for sepsis can be exposed to risks associated with unnecessary antibiotics and intravenous fluids.
- **Inappropriate Settings:** This model was not trained or evaluated on patients receiving care in the ICU. Do not use this model in the ICU setting without further evaluation. This model was trained to identify the first episode of sepsis during an inpatient encounter. Do not use this model after an initial sepsis episode without further evaluation.
- **Clinical Rationale:** The model is not interpretable and does not provide rationale for high risk scores. Clinical end users are expected to place model output in context with other clinical information to make final determination of diagnosis.
- **Inappropriate decision support:** This model may not be accurate outside of the target population, primarily adults in the non-ICU setting. This model is not a diagnostic and is not designed to guide clinical diagnosis and treatment for sepsis.
- **Generalizability:** This model was primarily evaluated within the local setting of Duke University Hospital. Do not use this model in an external setting without further evaluation.
- **Discontinue use if:** Clinical staff raise concerns about utility of the model for the indicated use case or large, systematic changes occur at the data level that necessitates re-training of the model.

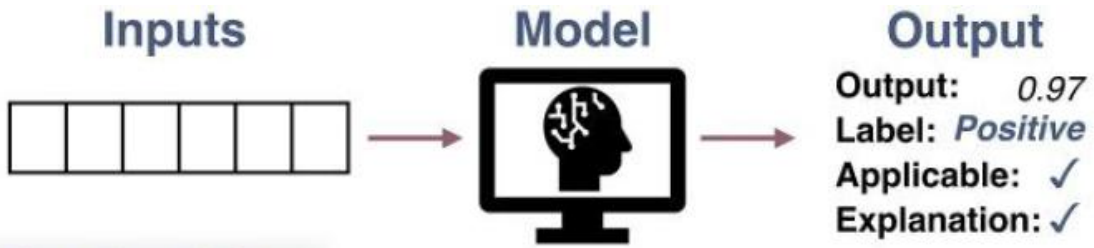
Other information:

- **Outcome Definition:** https://doi.org/10.1101/648907
- **Related model:** http://doi.org/10.1001/jama.2016.0288
- **Model development & validation:** arxiv.org/abs/1708.05894
- **Model implementation**: jmir.org/preprint/15182
- **Clinical trial:** clinicaltrials.gov/ct2/show/NCT03655626
- **Clinical impact evaluation:** TBD
- **For inquiries and additional information:** please email mark.sendak@duke.edu

Sendak MP, et al. npj Digit. Med. 2020, 3 (1), 41. - https://doi.org/10.1038/s41746-020-0253-3



https://www.iso.org/standard/87673.html (ISO 24051-1, figure based on CD2 final draft)

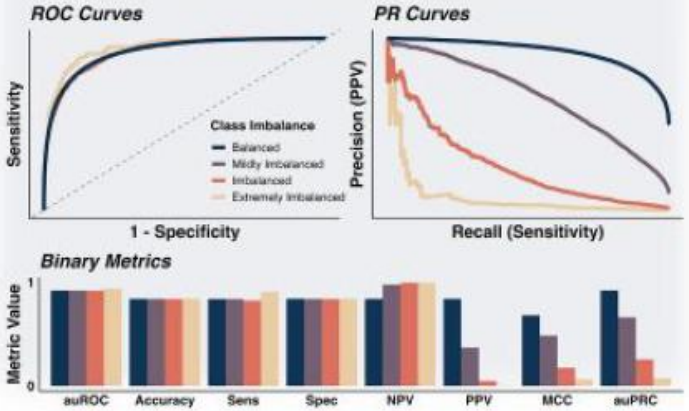


Applicability

Identifying inputs that diverge from training data *across* or *within* features.

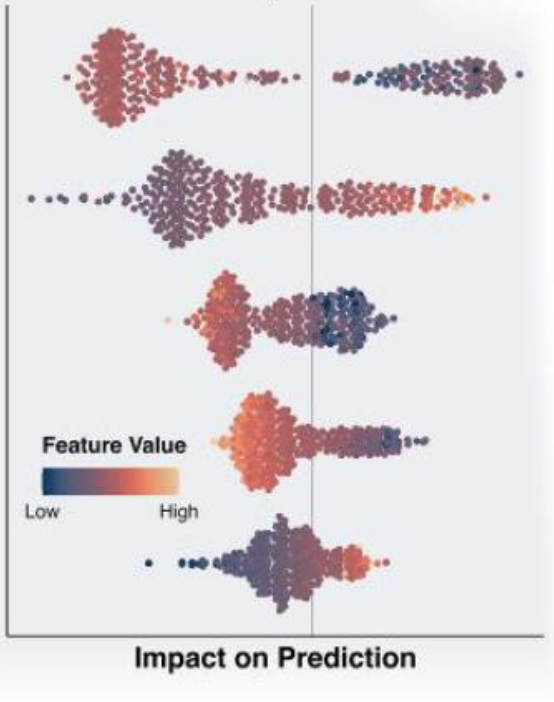
Metric Selection

Appropriately measuring pipeline performance.



Explainability

Estimating the impact of each feature on the final prediction

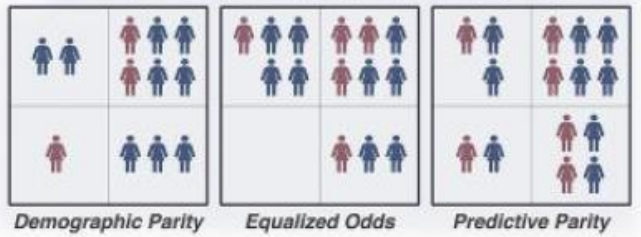


Ground Truth Definition

Evaluating all feasible options for assigning the gold-standard labels by which predictions are evaluated.

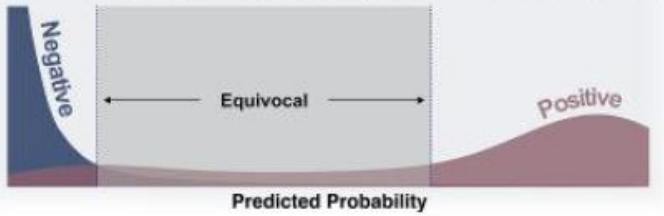
Algorithmic Fairness

Ensuring the model does not introduce or exacerbate inequity across populations



Threshold Optimization

Defining the optimal decision boundaries to convert continuous outputs into class labels



Spies NC, et al. *Clin Chem*. 2024; 70(11):1334–43.

CAP Laboratory Improvement Programs

Recommendations for Performance Evaluation of Machine Learning in Pathology

A Concept Paper From the College of American Pathologists

Matthew G. Hanna, MD; Niels H. Olson, MD; Mark Zarella, PhD; Rajesh C. Dash, MD; Markus D. Herrmann, MD, PhD; Larissa V. Furtado, MD; Michelle N. Stram, MD; Patricia M. Raciti, MD; Lewis Hassell, MD; Alex Mays, MD; Liron Pantanowitz, MD, PhD, MHA; Joseph S. Sirintrapun, MD; Savitri Krishnamurthy, MD; Anil Parwani, MD, PhD, MBA; Giovanni Lujan, MD; Andrew Evans, MD; Eric F. Glassy, MD; Marilyn M. Bui, MD, PhD; Rajendra Singh, MD; Rhona J. Souers, MS; Monica E. de Baca, MD; Jansen N. Seheult, MD

Table 7. Summary of Recommendations for Performance Evaluation of Machine Learning–Based Clinical Decision Support Systems in Pathology

1. Scope of guidance: performance evaluation of a clinically reported test result that includes a machine learning model in any portion of the test process and result
2. Clinical laboratories are required to perform verification and validation of machine-generated predictions in patient testing and follow mandated regulatory standards for maintaining quality systems for nonwaived testing
3. The scope of the performance evaluation should be guided by a comprehensive risk assessment to evaluate sources of variability and error and the potential for patient harm
4. Variations of verification and validation terminologies by different domains should be understood
5. Predeployment of the machine learning model includes the model properties, case mix/data compatibility, bias and ethics, and laboratory influences
6. Data sources for the performance evaluation should include diverse real-world data including all clinically meaningful variations to which the model may be exposed
7. An appropriate reference standard with comparable labels is required for performance evaluation
8. Clinical verification includes unmodified regulator-authorized machine learning models and should demonstrate that the laboratory performance characteristics matches those of the manufacturer (accuracy, precision, reportable range, reference intervals)
9. Clinical validation confirms with objective evidence that a modified regulator-authorized machine learning model or laboratory developed test establishing performance characteristics including accuracy, precision, analytical sensitivity, analytical specificity, reportable range, reference interval, and any other performance characteristic deemed necessary for appropriate evaluation of the test system
10. Suitable evaluation metrics and sample size calculations should be utilized for performance specifications based on the application
11. Precision studies ensure the machine learning model performance is maintained for the deployment laboratory
12. Change management and the appropriate documentation are critical to performance evaluation of machine learning models
13. Ongoing monitoring of patient testing that includes machine learning models is needed to mitigate performance shift and drift and to ensure stability and reliability over time
14. Inclusion of human factor evaluation during performance evaluation safeguards model explainability and trust
15. Personnel training and competency evaluation planning should be included for all personnel involved in the patient testing process in an end-to-end fashion

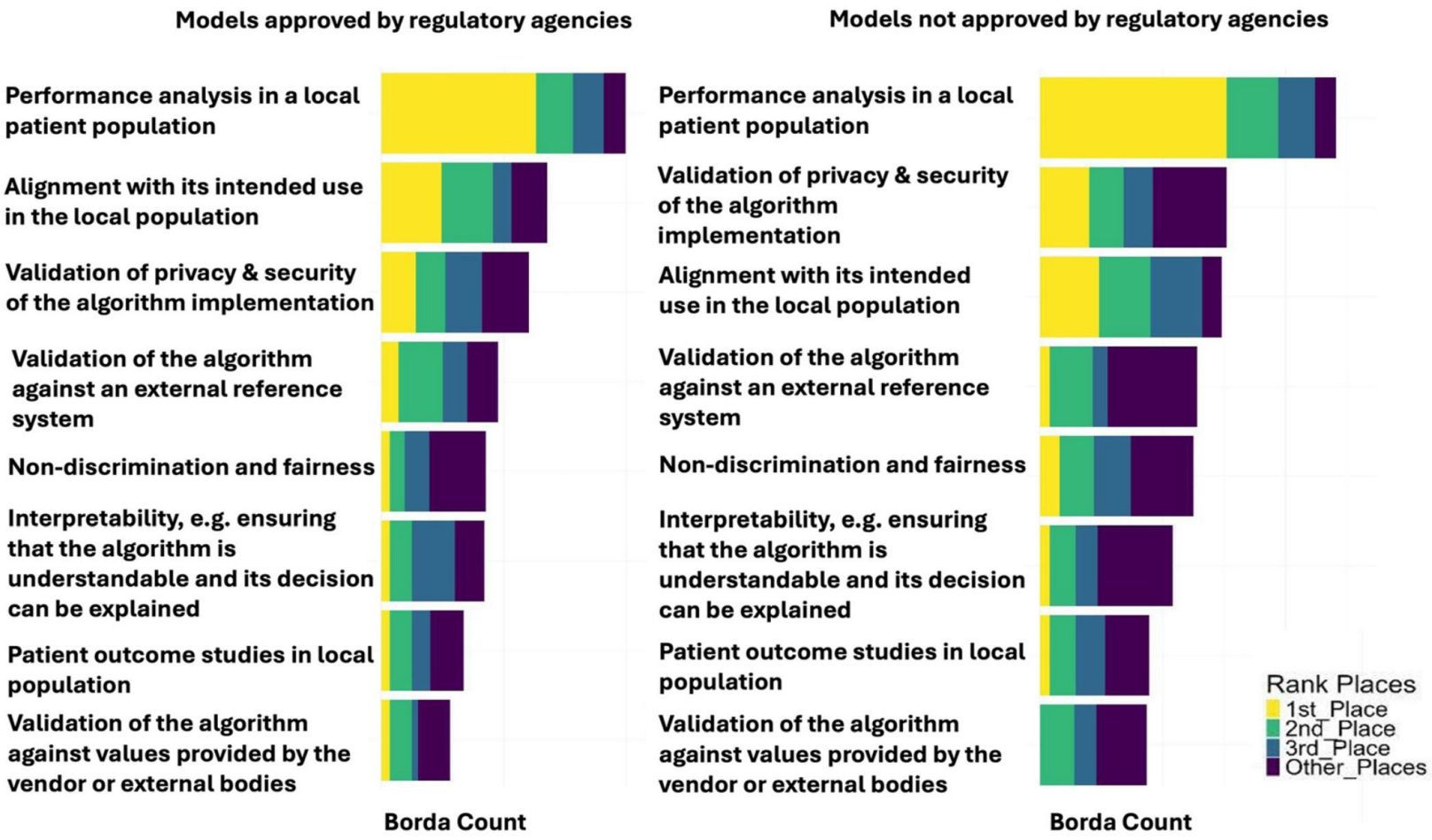
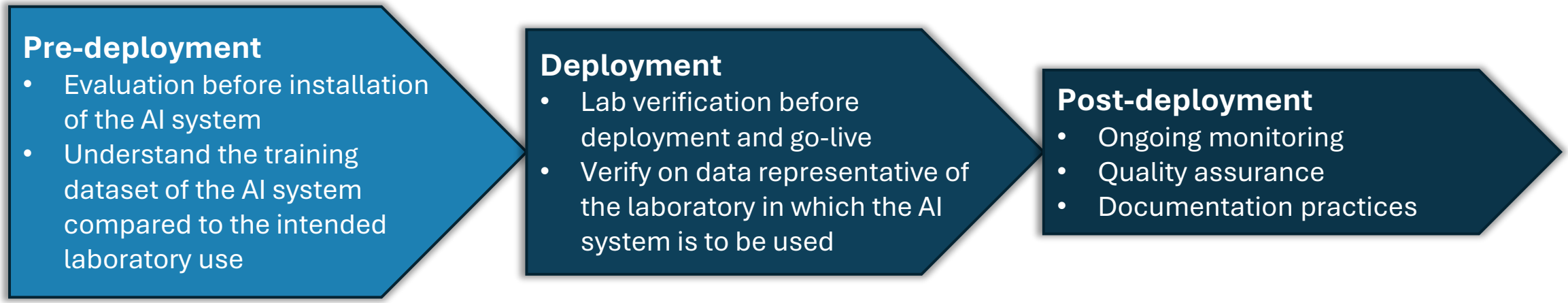


Figure 2: Prioritization of verification studies for both approved and non-approved machine learning models. Each bar represents the cumulative Borda count for a given priority, with color indicating the ranking places: yellow=1st place, green=2nd place, blue=3rd place, and purple=other places.

Yang HS, et al. Clin Chem Lab Med (CCLM). 2026 [Ahead of print] - https://doi.org/10.1515/cclm-2025-1322.



https://www.iso.org/standard/87673.html (ISO 24051-1, figure based on CD2 final draft)

Key Roles and Responsibilities

Subject Matter Experts

- Align implementation to fit unmet clinical need.
- Evaluate failure modes and off-target effects.

Data Scientists & Data Engineers

- Build and evaluate models for deployment.
- Optimize storage and retrieval of input data.

Software & ML Engineers

- Build robust and secure prediction pipelines.
- Implement best practices in DevOps/MLOps.

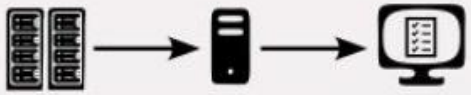
Information Technology & Systems

- Maintain interfaces for ML inputs and outputs.
- Develop infrastructure and allocate resources.

Terms and Technologies

Development Environment

Before deployment, the **full pipeline** should be **robustly tested** in an offline "**sandbox**" that is **completely isolated** from clinical workflows.



Deployment

Deploying a model to a ***server*** makes it **accessible** to other systems or users within a **network**.

MLOps

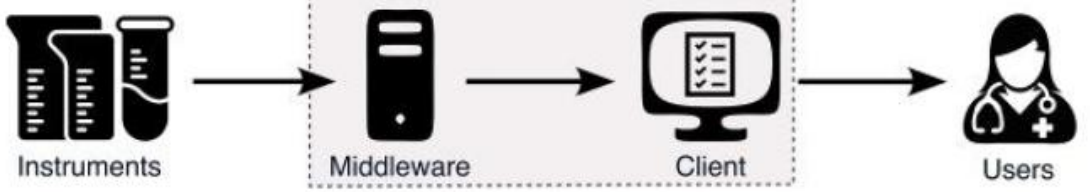
The framework for **building**, **deploying**, and **monitoring** end-to-end ML solutions in live, **production environments** safely and effectively.

Logging Metrics

Latency: *Turn-around time for predictions.*

Uptime: *% of time a prediction can be made.*

Scalability: *Change in latency/uptime with increased volume.*



Spies NC, et al. *Clin Chem*. 2024; 70(11):1334–43.

Lab-developed model

Data accessibility

Model development

Model validation and implementation

Legal requirements (IVDR/MDR/AI Act)

Literature-derived model

Data accessibility

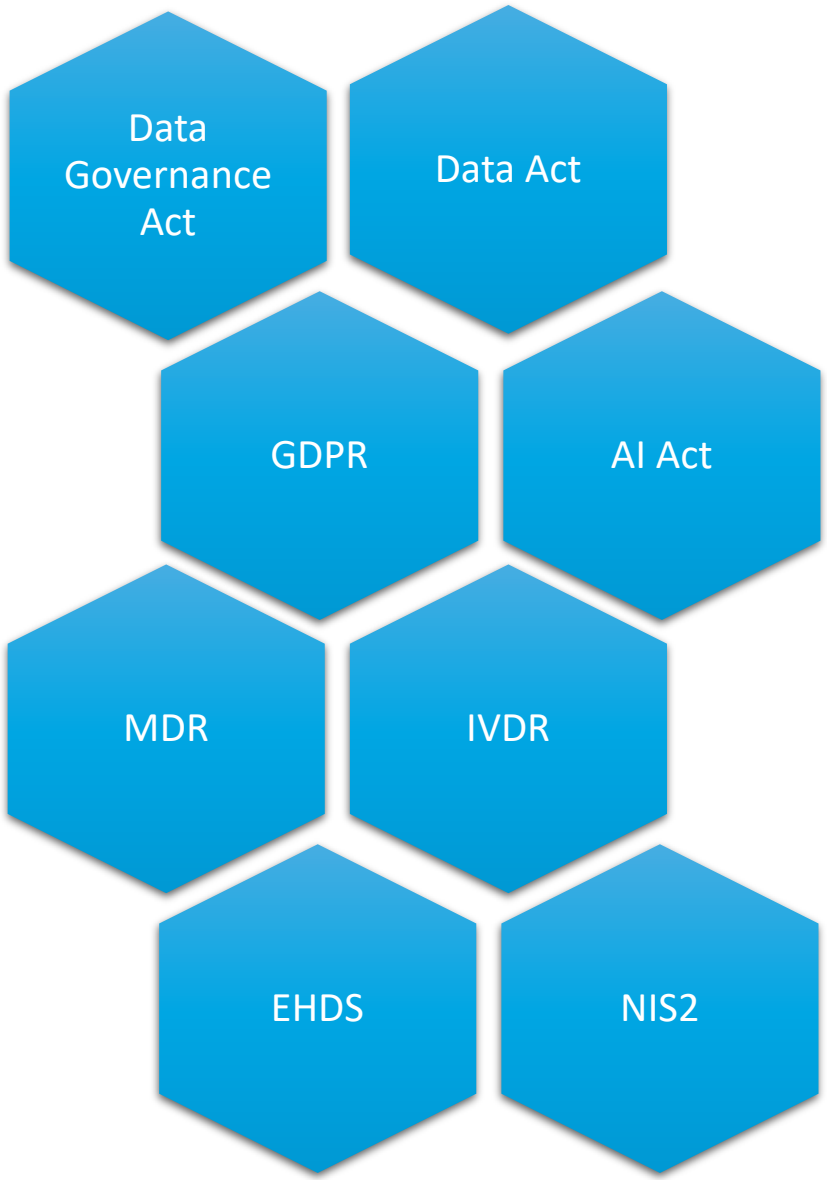
Model validation and implementation

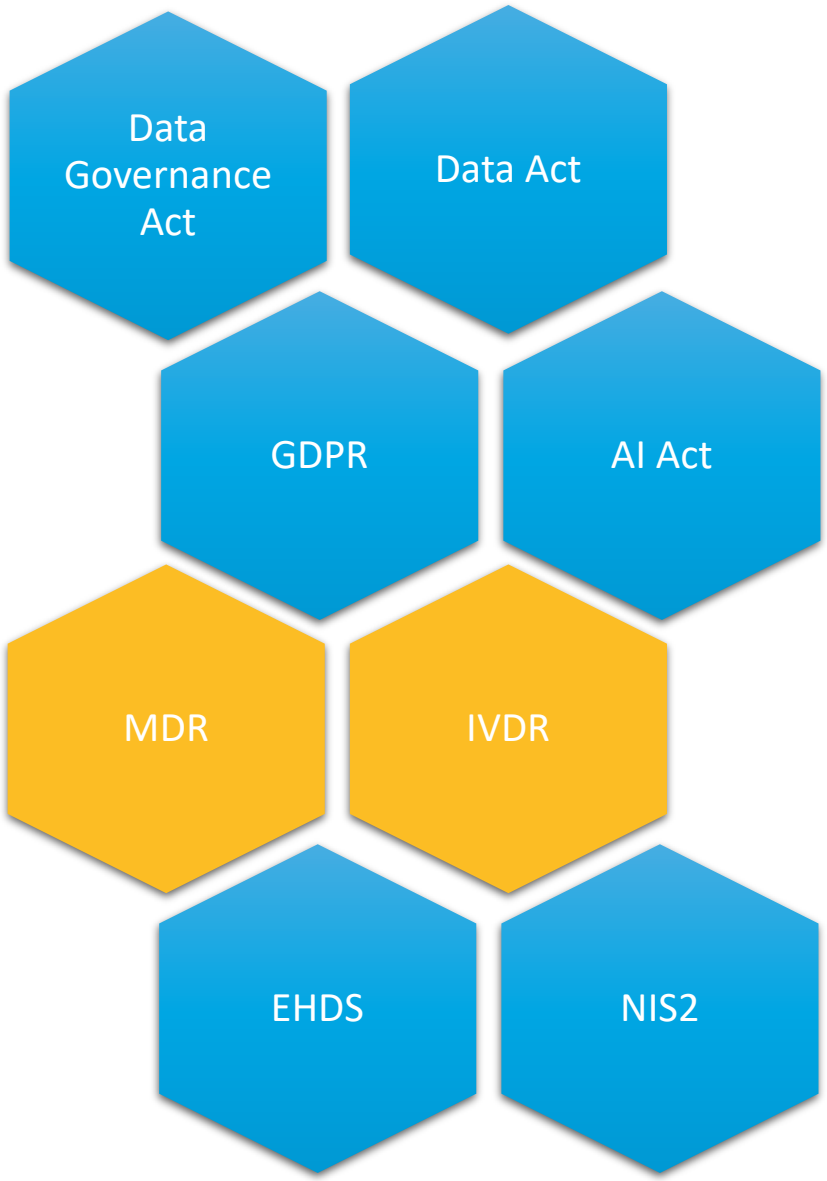
Legal requirements (IVDR/MDR/AI Act)

Off-the-shelf commercial application

Data accessibility

Model validation and implementation


Data Governance Act
Data Act
GDPR
AI Act
MDR
IVDR
EHDS
NIS2



MDCG 2019-11

Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR

CE Tool

NL | EN

Home | Applicable legislation | MDR | IVDR | Need help? | About us

Home > What applies to me?

Is your device or software a medical device?

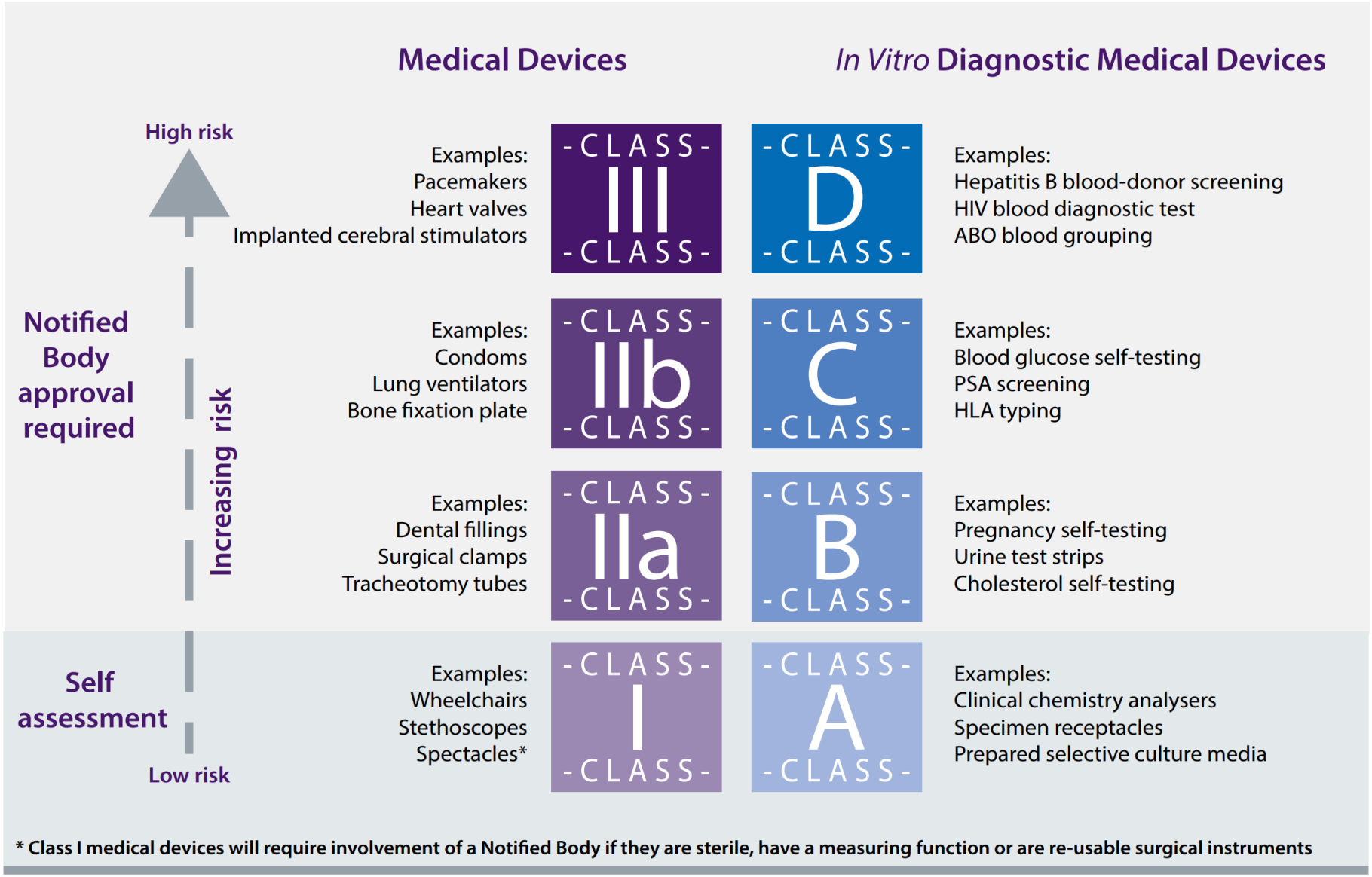
Directly to the quick scan

https://cetool.nl/en

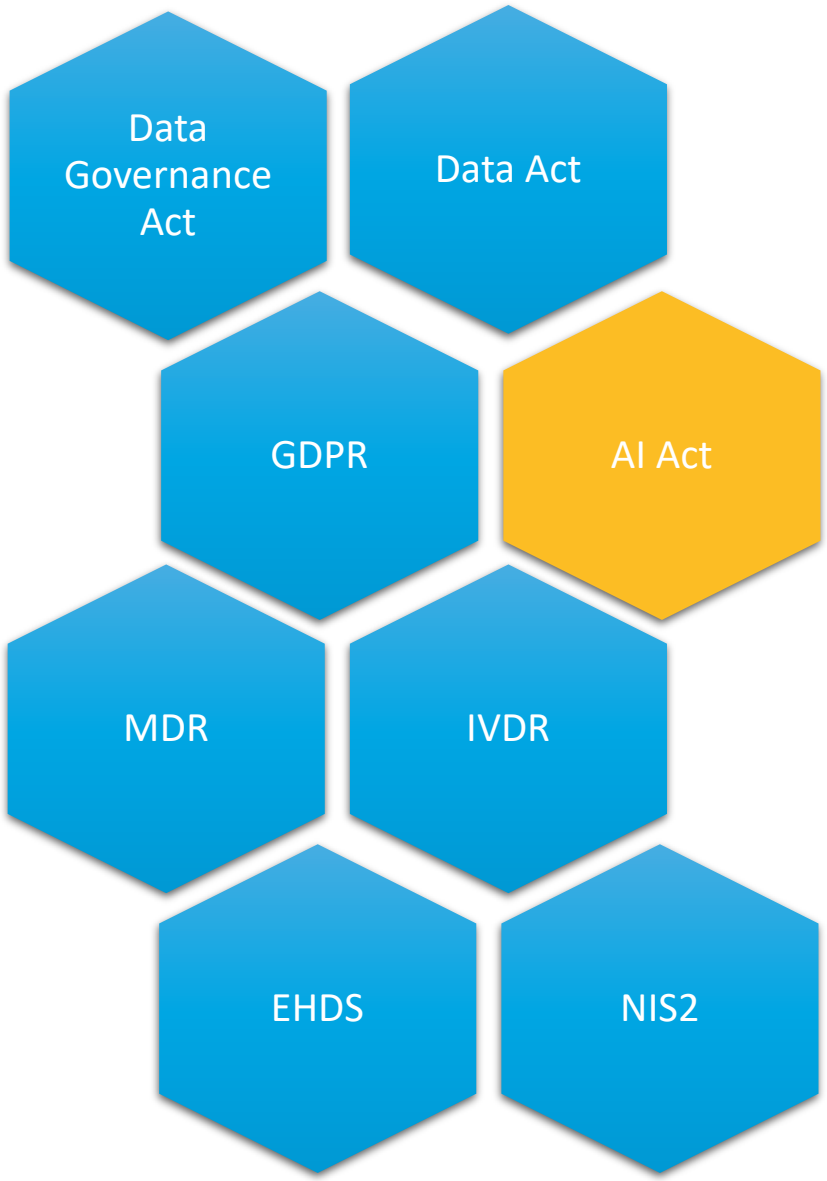
Quick scan medical device

Answer the questions to find out whether your device is considered to be a medical device regulated by the MDR or IVDR, and hence will need to obtain a CE certification. If you have any doubts about the results of the quick scan, always consult an expert.

Start the quick scan



Sara Payne, Alison Hall (PHG Foundation). Briefing note: what is the IVDR? 2018



Banned

AI Systems used for certain biometric identification, biometric categorisation, emotion recognition in certain domains, social scoring, subliminal manipulation

High Risk AI Systems (HRAIS)

AI systems used as products or safety components of a product covered by Annex I (incl. medical devices, toys, machinery) and Annex III (e.g. other biometric systems, critical infrastructure, education, employment, justice, immigration, law enforcement and democratic contexts)

General Purpose AI systems (GPAI)

Two-tiered model of regulation:

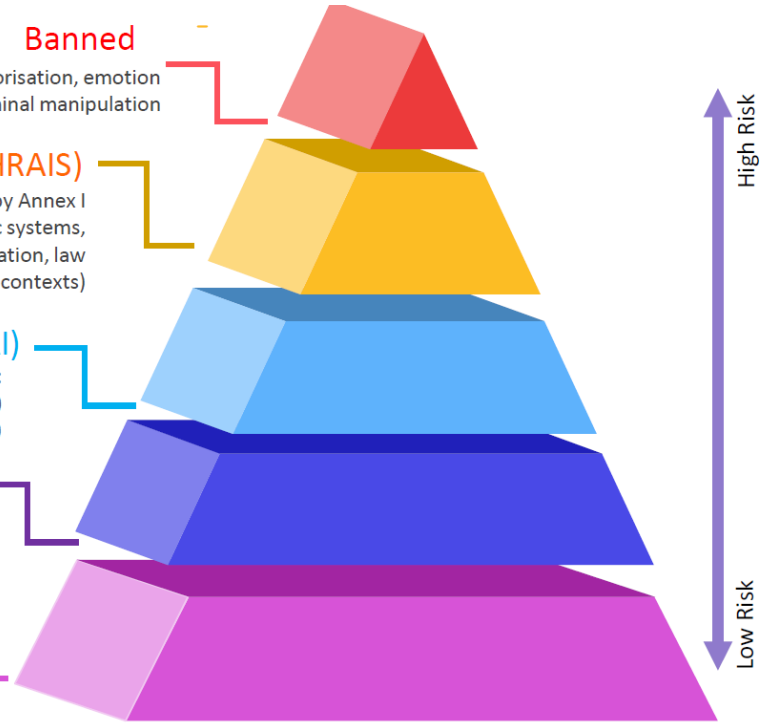
- GPAI models with systemic risk (onerous obligations)
- all other GPAI models (more limited obligations)

AI Systems intended to interact with natural persons

e.g. chatbots (subject to transparency requirements)

Other AI Systems

All AI Systems should comply with general principles
Codes of conduct may be introduced for all low-risk AI systems



EU AI Act Tool - 6 crucial questions

1. Is the system prohibited under the AI Act?
2. Is the system a high-risk system (type 1 / type 2)?
3. Do any additional transparency requirements apply?
4. Is it an AI system / model or GPAIM (General-Purpose AI Model)?
5. Who is who in the EU AI Act?
6. What corresponding obligations apply?

For each of the 6 steps, the tool guides you in answering the questions mentioned above. This enables you to make an first assessment of the potential impact of the EU AI Act on your project.

https://data-en-maatschappij.ai/en/tools/the-eu-ai-act-in-6-steps-2

THE IMPACT OF THE EU AI ACT IN 6 SIX STEPS

Step 2: Is the system a high-risk system (type 1)?

If the AI system is not a prohibited AI system under article 5 AI Act, attention must be given to the high-risk AI systems listed in **article 6 of the AI Act**. These systems could pose a serious risk to the health or safety of individuals or their fundamental rights.

The high-risk AI systems can be divided in **two types**.

- The first type relates to **products to which sectoral, European product legislation already applies**. If an organization is already involved with products or safety components for these kind of products, they may already be aware that specific legislation applies and that conformity assessments must be done.
- The second type of high-risk AI systems are systems used for a **specific purpose in a specific context or sector**. If both the purpose and context are present, the system is high-risk.

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Type 1 – Relevant products under specific legislation (Annex I)

The system is high-risk when it is (part of) a product that falls within one of the specified legislation (or is a safety component of such a product) in Annex I **and requires a third-party conformity assessment** by a third party under said legislation. A safety component is a component of a product or of an AI system which fulfils a safety function for that product or AI system, or the failure or malfunctioning of which endangers the health and safety of persons or property.

Be aware: the product categories may be broader than anticipated. For instance—radio equipment does not only include radios. It includes TVs, radio receivers, devices that connect to public telecom networks, cordless phones, mobile phones, and more. Therefore, in case of doubt about whether the AI system is a (safety component of a) product in one of the categories, it is recommended to look further into the respective definitions.

EXCEPTIONS

Civil aviation, two- or three-wheel vehicles or quadricycles, agricultural and forestry vehicles, marine equipment, rail systems, motor vehicles and their trailers, drones. These are not subject to the obligations for high-risk AI systems in the AI Act.

Medical Devices
Joint Artificial Intelligence Board and
Medical Device Coordination Group Document

AIB 2025-1
MDCG 2025-6

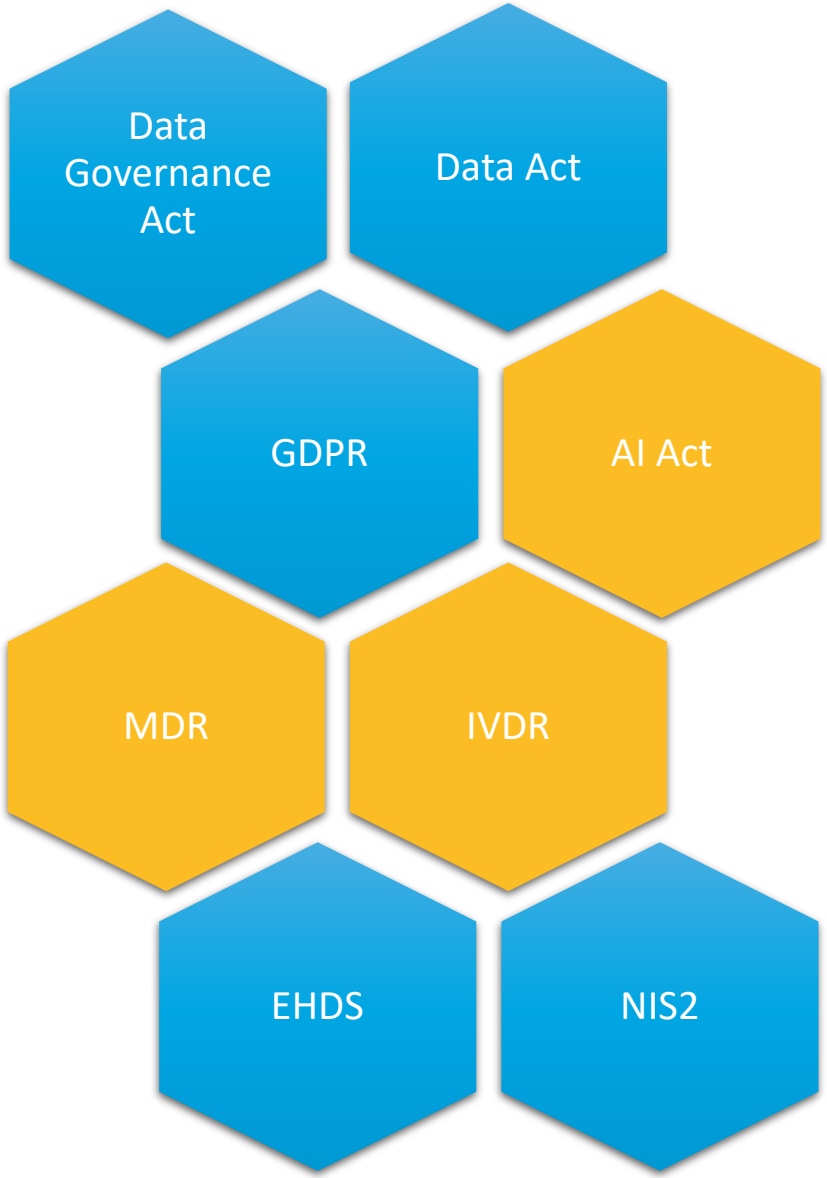
AIB 2025-1

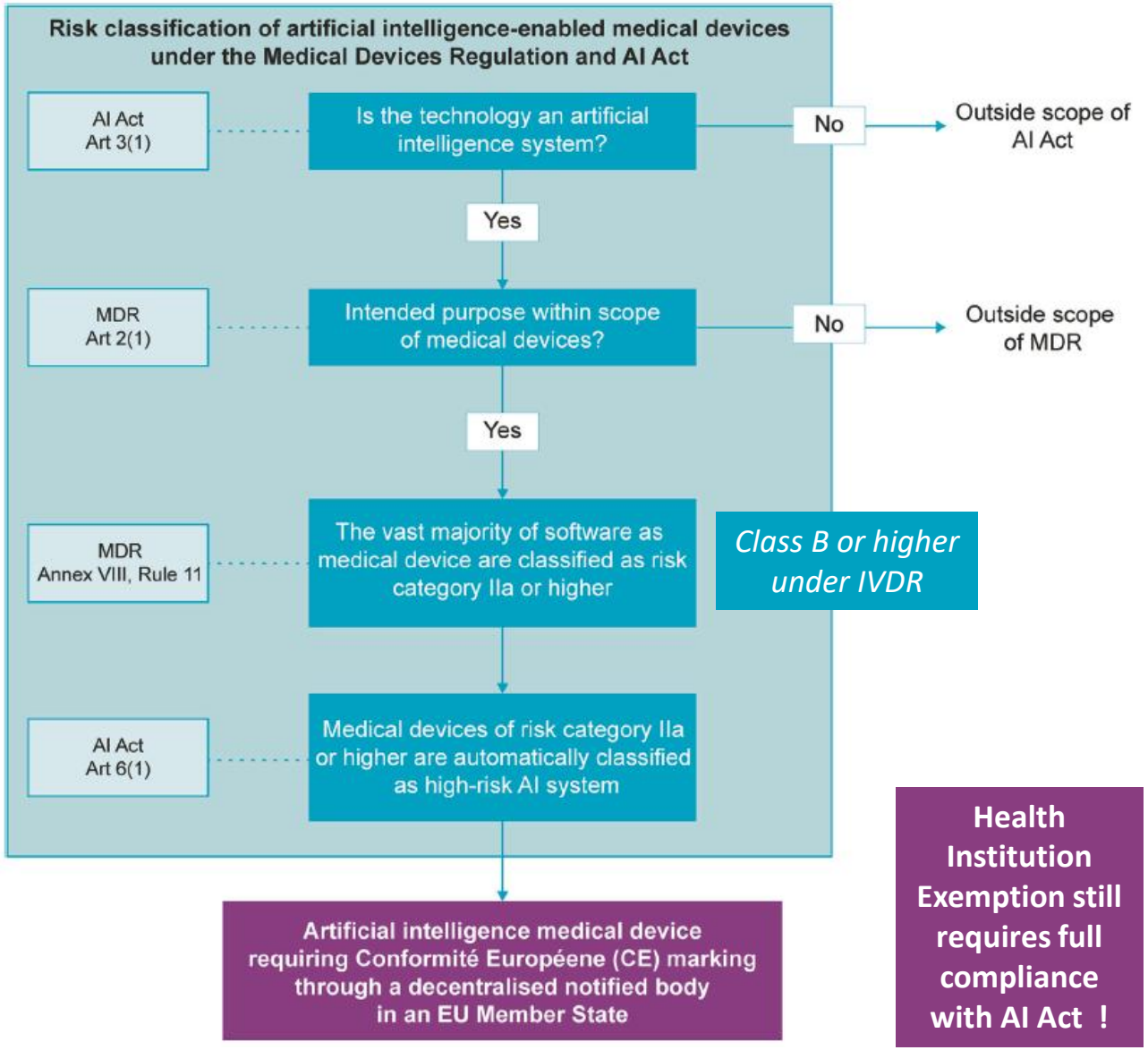
MDCG 2025-6

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

June 2025

https://health.ec.europa.eu/document/download/b78a17d7-e3cd-4943-851d-e02a2f22bbb4_en





Schmidt J, et al. *npj Digit Med.* 2024;7(1):229.

Requirements for providers of high-risk AI systems (Art. 8–17)

High risk AI providers must:

- Establish a **risk management system** throughout the high risk AI system's lifecycle;
- Conduct **data governance**, ensuring that training, validation and testing datasets are relevant, sufficiently representative and, to the best extent possible, free of errors and complete according to the intended purpose.
- Draw up **technical documentation** to demonstrate compliance and provide authorities with the information to assess that compliance.
- Design their high risk AI system for **record-keeping** to enable it to automatically record events relevant for identifying national level risks and substantial modifications throughout the system's lifecycle.
- Provide **instructions for use** to downstream deployers to enable the latter's compliance.
- Design their high risk AI system to allow deployers to implement **human oversight**.
- Design their high risk AI system to achieve appropriate levels of **accuracy, robustness, and cybersecurity**.
- Establish a **quality management system** to ensure compliance.

Timelines

- After entry into force, the AI Act will apply by the following deadlines:
  - 6 months for prohibited AI systems.
  - 12 months for GPAI.
  - 24 months for high risk AI systems under Annex III.
  - 36 months for high risk AI systems under Annex I.

2/8/2027

EU Artificial Intelligence Act. High-level summary of the AI Act [website]. 2024

EUDAMED access date: February 7, 2025

✓ Medical device software (MDSW), n = 89

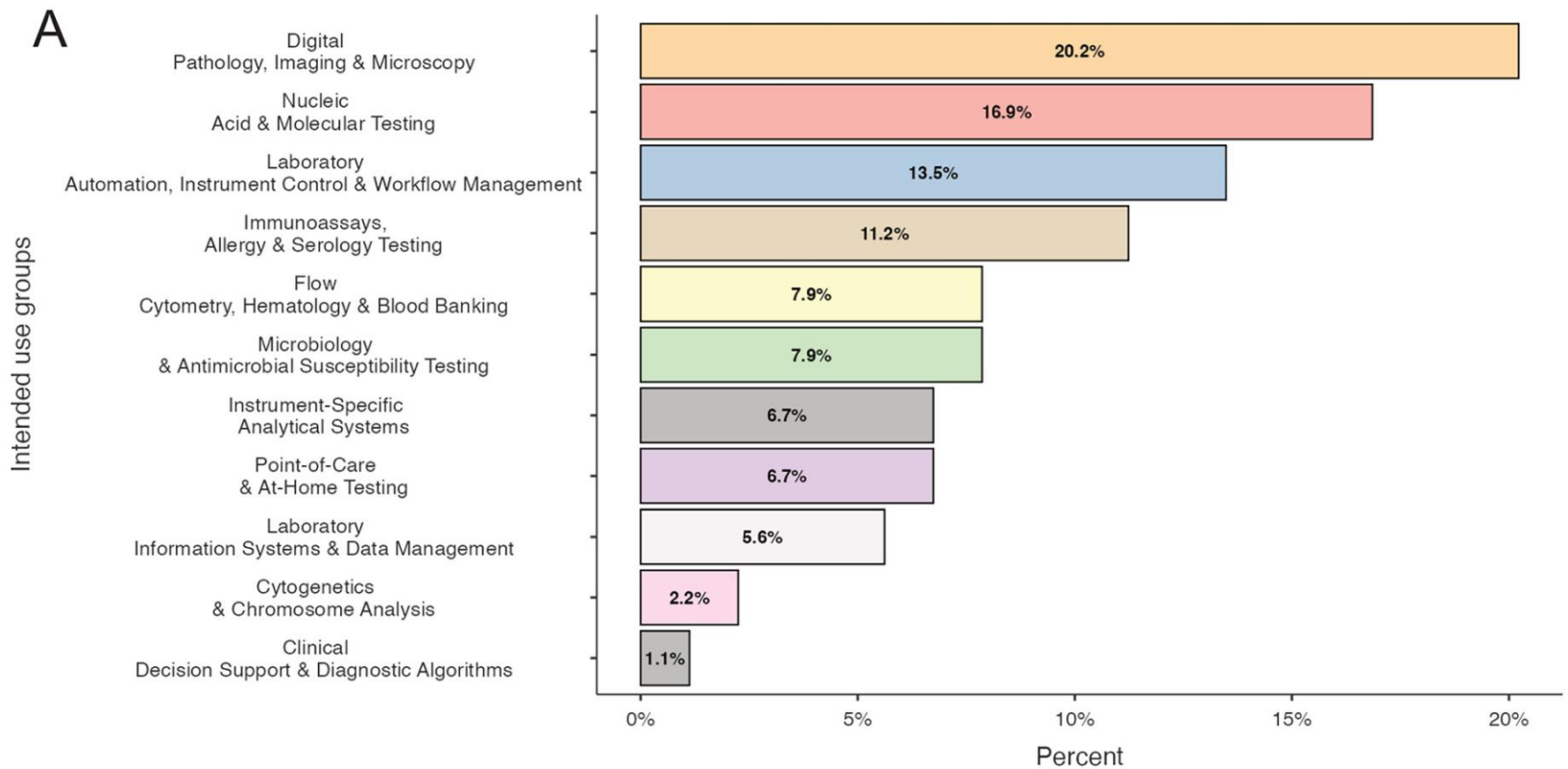


Figure 2: Intended use groups and EU market distribution of medical devices. (A) Distribution of medical devices by intended use group.

Çubukçu HC, et al. Clin Chem Lab Med (CCLM). 2025;63(10):1891-1914.

EUDAMED access date: February 7, 2025

- ✓ Medical device software (MDSW), n = 89
- ✓ 11 x AI software: Class A (n = 7) and Class C (n = 4)

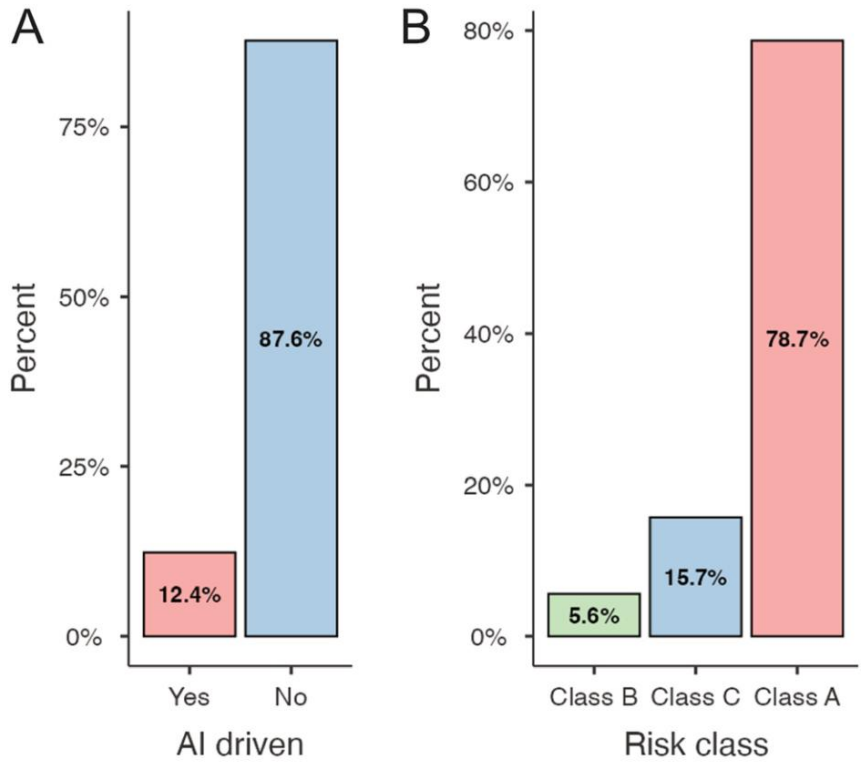


Figure 3: Proportion of AI-driven devices and device risk classifications. (A) Distribution of medical devices based on AI integration. (B) Classification of devices by risk level.

Çubukçu HC, et al. Clin Chem Lab Med (CCLM). 2025;63(10):1891-1914.

Example of class A AI MDSW

Automated Workflows with ASI's Digital Cytogenetics Platform

ASI's cytogenetics platform is a **versatile** imaging and analysis solution offering chromosome review and computer-aided karyotyping **(HiBand)**, automated FISH analysis **(HiFISH)** or a combination of both **(CytoPower)**. The platform also features **HiSKY**, ASI's renowned gold standard for spectral karyotyping (multi-color FISH analysis).

Supporting both **single and multiple readers**' workflows, the platform provides standardized and consistent results across multiple sample types, staining techniques, and vendor-agnostic probes. Adjustable to address laboratories' needs, the platform offers a range of **image acquisition solutions**, from 1-slide manual capture to 9-slide scanner and 99+ slide tray loader.

Digital Karyotyping: Boosting Lab Productivity

Metaphase Search & Mitotic Index Calculation at 10X

Metaphase Scanning & Cell Type Detection at 100X

Optional Sorting by Karyotype Quality

Computer-Aided Chromosome Segmentation

Computer-Aided Chromosome Classification*

Correctly segmented

93% BL | **90%** BM

Correctly classified

99% BL | **96%** BM

* Following manual adjustments to correct automatic segmentation

https://spectral-imaging.com/wp-content/uploads/2025/10/Cytogenetics-Brochure-2025_505-Rev.-D.pdf

Conclusion

Take away messages

To facilitate the implementation of AI in our labs, we need:

- Specific **education** on (the implementation of) AI in laboratory medicine
- Knowledge about **data** types, data access and data sharing
- A frame-work for the implementation of AI models under **IVDR/MDR**

UZ LEUVEN

Questions?