Implementation of the **Guideline** for high-quality diagnostic and prognostic applications of **AI** in **healthcare**

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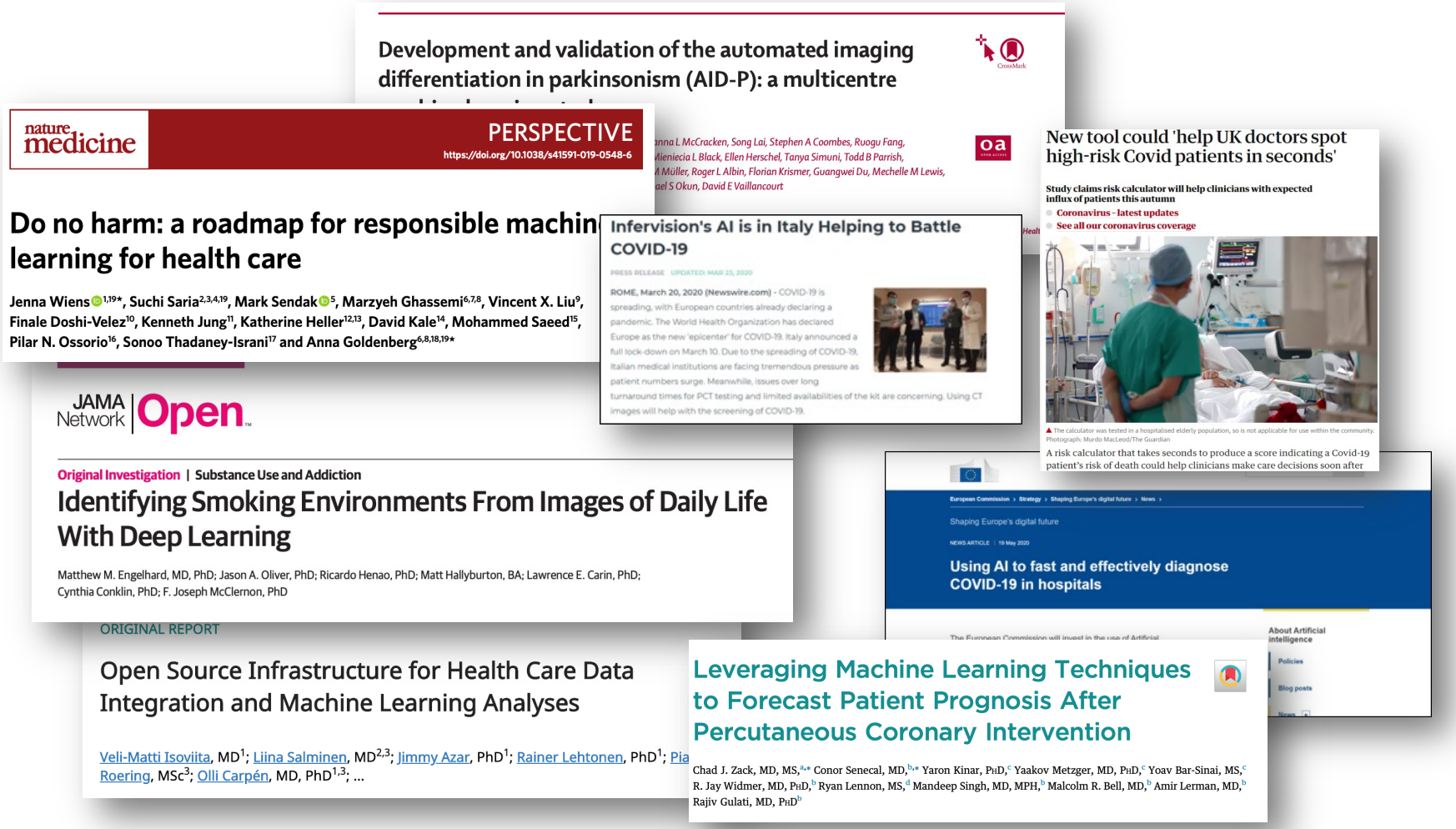
UMC Utrecht

Leids Universitair Medisch Centrum

Why a guideline? **AI everywhere** in healthcare.



Definition

AIPA (AI Prediction Algorithm):

An algorithm that leads to

a prediction of a health outcome in individuals.

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Diagnostic = predicting a current outcome (e.g., instead of directly using an invasive test)

Prognostic = predicting a future event/outcome

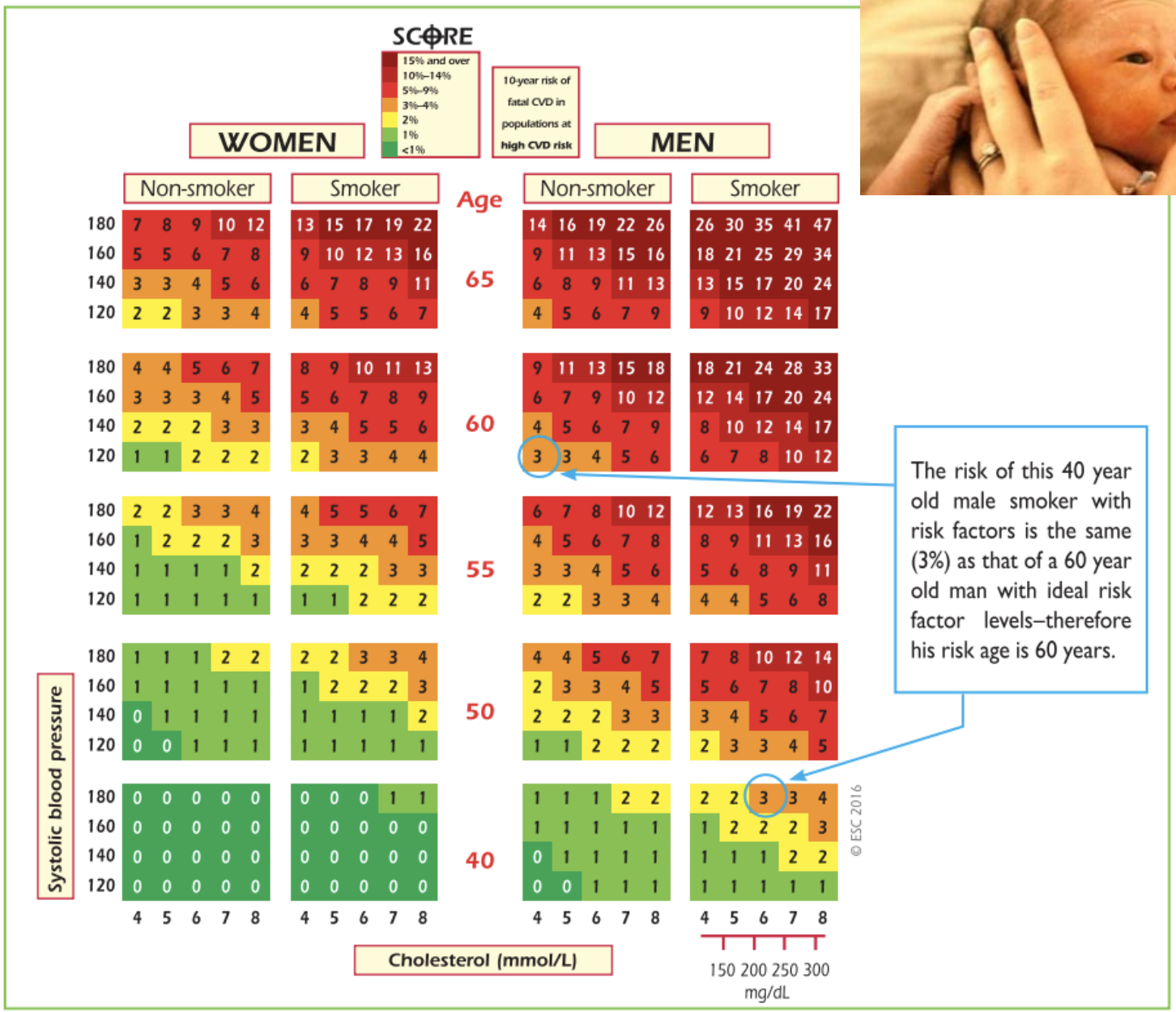


Figure 4 SCORE chart (for use in high-risk European countries) illustrating how the approximate risk age can be read off the chart. SCORE = Systematic Coronary Risk Estimation.

*Authors/Task Force Members, Piepoli MF, Hoes AW, Agewall S, Albus C, Brotons C, Catapano AL, Cooney MT, Corrà U, Cosyns B, Deaton C. 2016 European Guidelines on cardiovascular disease prevention in clinical practice: Developed with the special contribution of the European Association for Cardiovascular Prevention & Rehabilitation (EACPR). European Journal of Preventive Cardiology. 2016 Jul;23(11):NP1-96.

Scope: from development to implementation

Phase 0

Project idea and preparation

Phase 1

Collection and management of the Data

Phase 2

Development of the AIPA

Phase 3

Validation of the AIPA

Phase 4

Development of the required software

Phase 5

Impact assessment of the AIPA in combination with the software

Phase 6

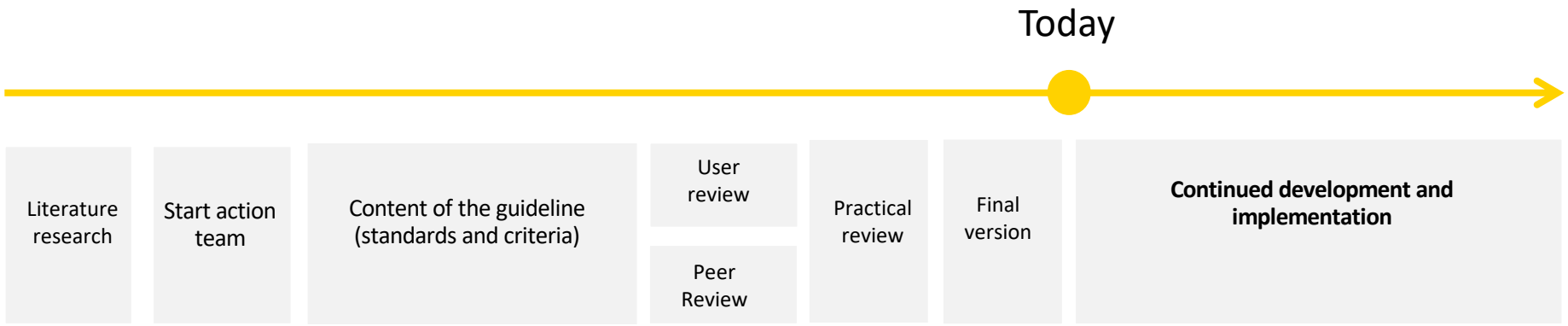
Implementation and use of the AIPA with software in daily practice

The **creation** of the guideline

Goal: collectively! create a standard which is

- ✓ Broadly applicable in the healthcare field.

Numerous working group meetings with experts (from all stakeholders) to determine and prioritize most important topics per phase and described the quality standards.



Targeted **groups**

Applying AI

Healthcare provider
Professional Scientific
Medical associations
Education/training
IT suppliers
Patient / Citizen

Developing AI

Validator
Responsible
developer
Researcher
Data manager Data
supplier

Assessing AI

(Internal)
supervisor
Notified body Peer
reviewer Privacy
officer Insurer

Society

Patient(s)-
(associations)
Interest parties
Political parties
Interested citizen

Result: Guidance per phase, e-learning and community building

What is the guidance?

- What the healthcare field considers
  good professional conduct in
  the development, testing and implementation of an AIPA

- Starting point: available knowledge and the review

- Guideline is not legally binding

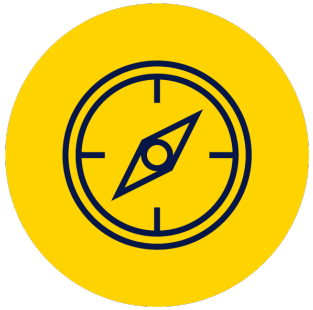
‘Comply or explain’

- Distinguishes between **requirements** and **recommendations**

- Requirements are indicated by:
  - ✓ **Mandatory**
  - ✓**(strongly) recommended**.

- Use of the field standard presupposes a comply or explain approach.

Phase 1 Data collection and management

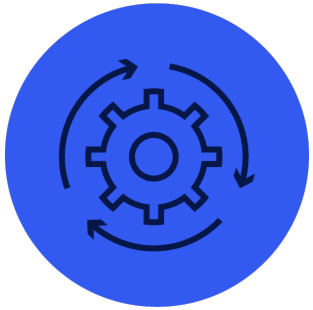


- Essential role in **the entire process** (all phases).

- Preparation, management and implementation of a **data management plan**

- Four core domains of the data management plan:
  - Data collection
  - Data availability
  - Metadata
  - Legal context

Phase 2 Development of the AIPA



- No step-by-step plan for model development (there is a lot of existing literature)
- No reporting guideline

Focus on **complete** and **accurate** description of all analysis and model steps

Main components of this phase:

- Derivation model
- Internal validation
- Robustness

Phase 3 Validation of the AIPA

External validation: **evaluation of predictions** (in data not used for development)

- Distinction between the evaluation:
  - Statistical properties
  - Clinical properties
  - Fairness and algorithmic bias

- No minimum requirements for predictive performance (context dependent)

Phase 4 Development of the required software

- ☐ Tailoring design and explanation model to the **end user**
- ☐ **A digital leaflet** for the end user about the use of the AIPA
- ☐ Drawing up a **monitoring plan**
- ☐ **Security** and **testing** software (largely covered by existing standards)

Phase 5 Impact assessment of the AIPA with the software

Determining the **effect** of using the AIPA in the intended medical practice.

- ❑ Map the **expected effect** on medical processes and health outcomes
- ❑ Estimate possible **risks**
- ❑ Explicit **interaction** AIPA with care process and care provider.
- ❑ Set up a **comparative study**. Carry out a **pilot** or feasibility study in advance.

Phase 6 Implementation and use in daily practice

An **implementation plan** with focus on:

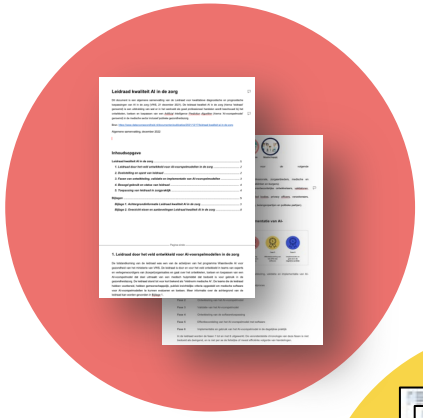
- ☐ Technical implementation
- ☐ Embedding the use of AIPA in existing work processes

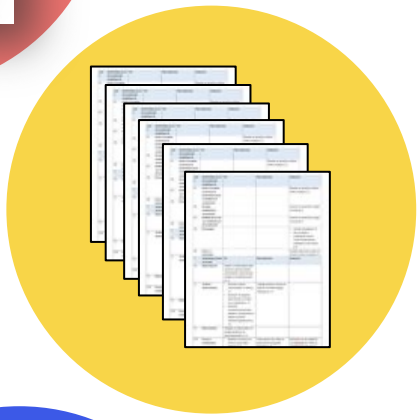
Monitoring on, among other things:

- ☐ Technical errors
- ☐ Incorrect use
- ☐ Unexpected side effects

Education and **information** about the AIPA for the end user and /or healthcare organization.

Implementation





To get **started?**

- The guideline
- Four-page summary
- An online short course
- Recommendation table per phase
- Overview of important aspects per phase
- Templates (e.g., data management, monitoring)

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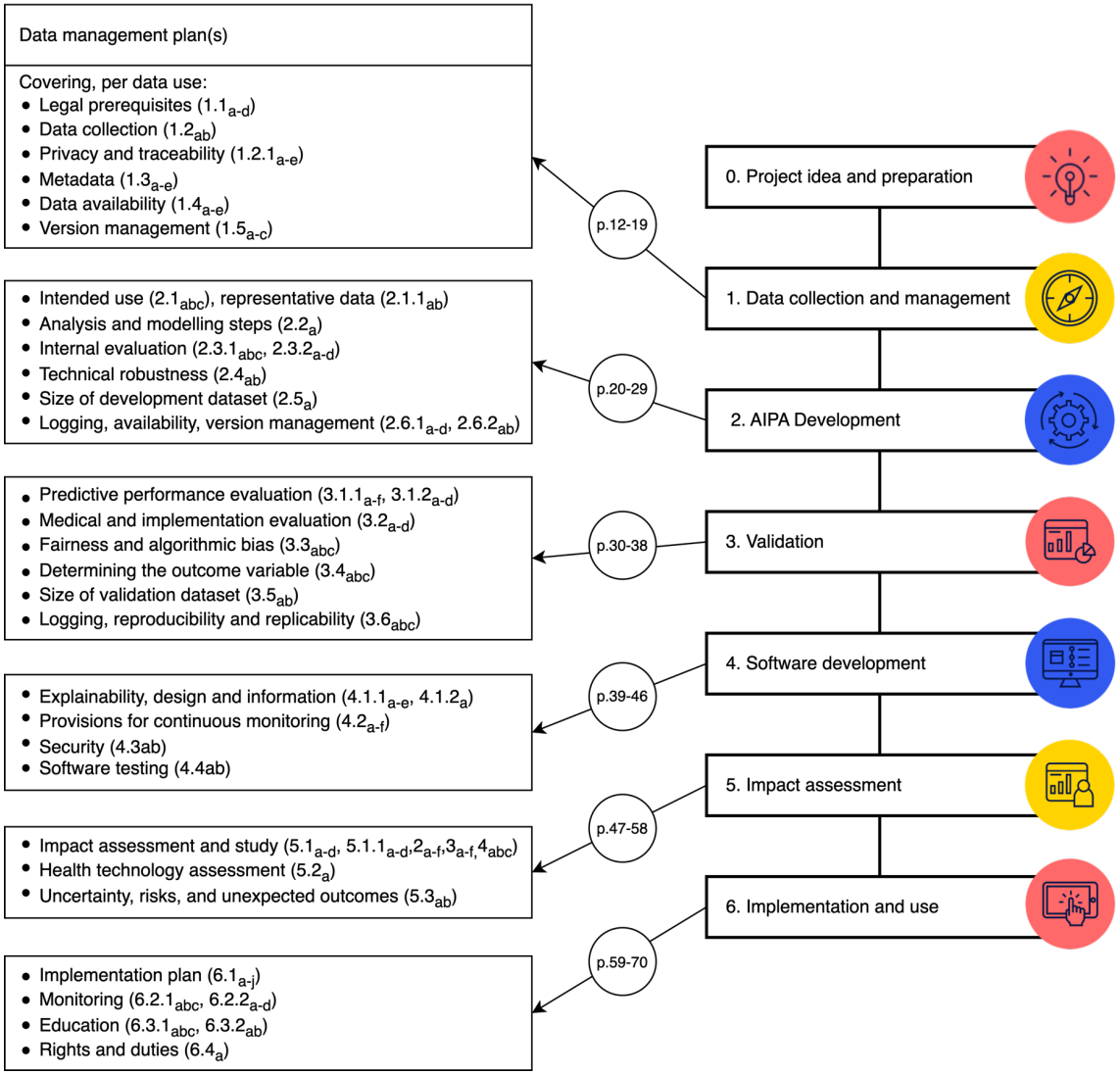
Contents of the guideline



Thank you!

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