

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

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REVIEW ARTICLE OPEN Check for updates

## Guidelines and quality criteria for artificial intelligence-based prediction models in healthcare: a scoping review

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Ministerie van Volksgezondheid, Welzijn en Sport

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### Guideline for high-quality diagnostic and prognostic applications of AI in healthcare

This guideline provides a description of what the work field considers good professional conduct in the development, testing and implementation of an Artificial Intelligence Prediction Algorithm (AIPA) in the medical sector, including public healthcare.

**Download 'Guideline for high-quality diagnostic and prognostic applications of AI in healthcare'**

PDF document | 80 pagina's | 713 kB  
Publicatie | 28-12-2021

[The Dutch version of the guideline AI in healthcare.](#)



[www.leidraad-ai.nl](http://www.leidraad-ai.nl)



DOI: 10.17605/OSF.IO/TNRJZ



# Why a guideline? AI everywhere in healthcare.

## Development and validation of the automated imaging differentiation in parkinsonism (AID-P): a multicentre



nature  
medicine

PERSPECTIVE

<https://doi.org/10.1038/s41591-019-0548-6>

Anna L. McCracken, Song Lai, Stephen A. Coombes, Ruogu Fang, Alenecia L. Black, Ellen Herschel, Tanya Simuni, Todd B. Parrish, A. Müller, Roger L. Albin, Florian Krismer, Guangwei Du, Mechelle M. Lewis, Angel S. Okun, David E. Vaillancourt



## Do no harm: a roadmap for responsible machine learning for health care

Jenna Wiens<sup>1,19\*</sup>, Suchi Saria<sup>2,3,4,19</sup>, Mark Sendak<sup>5</sup>, Marzyeh Ghassemi<sup>6,7,8</sup>, Vincent X. Liu<sup>9</sup>, Finale Doshi-Velez<sup>10</sup>, Kenneth Jung<sup>11</sup>, Katherine Heller<sup>12,13</sup>, David Kale<sup>14</sup>, Mohammed Saeed<sup>15</sup>, Pilar N. Ossorio<sup>16</sup>, Sonoo Thadaneey-Israni<sup>17</sup> and Anna Goldenberg<sup>5,8,18,19\*</sup>

## Infervision's AI is in Italy Helping to Battle COVID-19

PRESS RELEASE | UPDATED: MAR 23, 2020

ROME, March 20, 2020 (NewsWire.com) - COVID-19 is spreading, with European countries already declaring a pandemic. The World Health Organization has declared Europe as the new 'epicenter' for COVID-19. Italy announced a full lock-down on March 10. Due to the spreading of COVID-19, Italian medical institutions are facing tremendous pressure as patient numbers surge. Meanwhile, issues over long turnaround times for PCT testing and limited availabilities of the kit are concerning. Using CT images will help with the screening of COVID-19.



## New tool could 'help UK doctors spot high-risk Covid patients in seconds'

Study claims risk calculator will help clinicians with expected influx of patients this autumn

- Coronavirus - latest updates
- See all our coronavirus coverage



▲ The calculator was tested in a hospitalised elderly population, so is not applicable for use within the community. Photograph: Marko Matkovic/The Guardian

A risk calculator that takes seconds to produce a score indicating a Covid-19 patient's risk of death could help clinicians make care decisions soon after

JAMA  
Network | Open

Original Investigation | Substance Use and Addiction

## Identifying Smoking Environments From Images of Daily Life With Deep Learning

Matthew M. Engelhard, MD, PhD; Jason A. Oliver, PhD; Ricardo Henao, PhD; Matt Hallyburton, BA; Lawrence E. Carin, PhD; Cynthia Conklin, PhD; F. Joseph McClernon, PhD

ORIGINAL REPORT

## Open Source Infrastructure for Health Care Data Integration and Machine Learning Analyses

Veli-Matti Isoviita, MD<sup>1</sup>; Liina Salminen, MD<sup>2,3</sup>; Jimmy Azar, PhD<sup>1</sup>; Rainer Lehtonen, PhD<sup>1</sup>; Pia Roering, MSc<sup>3</sup>; Olli Carpén, MD, PhD<sup>1,3</sup>; ...

## Leveraging Machine Learning Techniques to Forecast Patient Prognosis After Percutaneous Coronary Intervention

Chad J. Zack, MD, MS,<sup>1\*</sup> Conor Senecal, MD,<sup>1,\*</sup> Yaron Kinar, PhD,<sup>2</sup> Yaakov Metzger, MD, PhD,<sup>3</sup> Yoav Bar-Sinai, MS,<sup>4</sup> R. Jay Widmer, MD, PhD,<sup>5</sup> Ryan Lennon, MS,<sup>4</sup> Mandeep Singh, MD, MPH,<sup>6</sup> Malcolm R. Bell, MD,<sup>6</sup> Amir Lerman, MD,<sup>7</sup> Rajiv Gulati, MD, PhD<sup>8</sup>

European Commission | Strategy | Shaping Europe's digital future | News

Shaping Europe's digital future

NEWS ARTICLE | 19 May 2020

### Using AI to fast and effectively diagnose COVID-19 in hospitals

The European Commission will invest in the use of Artificial Intelligence

About Artificial Intelligence

- Policies
- Blog posts
- News

# Definition

## **AIPA (AI Prediction Algorithm):**

An algorithm that leads to

a prediction of a health outcome in individuals.

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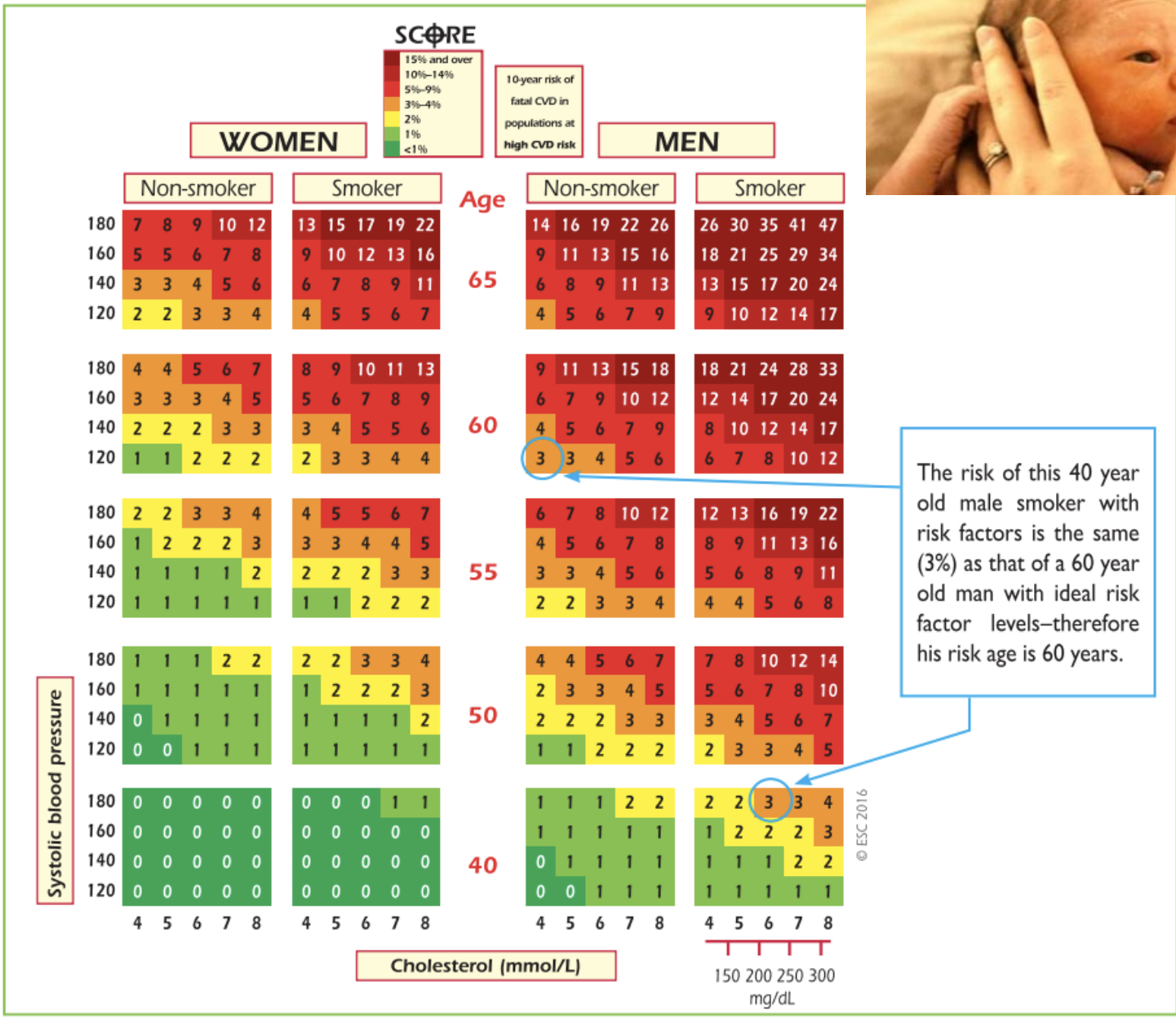
**Diagnostic** = predicting a current outcome (e.g., instead of directly using an invasive test)

**Prognostic** = predicting a future event/outcome





# What Is the Apgar Score?



The risk of this 40 year old male smoker with risk factors is the same (3%) as that of a 60 year old man with ideal risk factor levels—therefore his risk age is 60 years.

**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



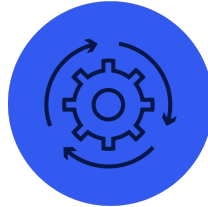
Phase 0

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

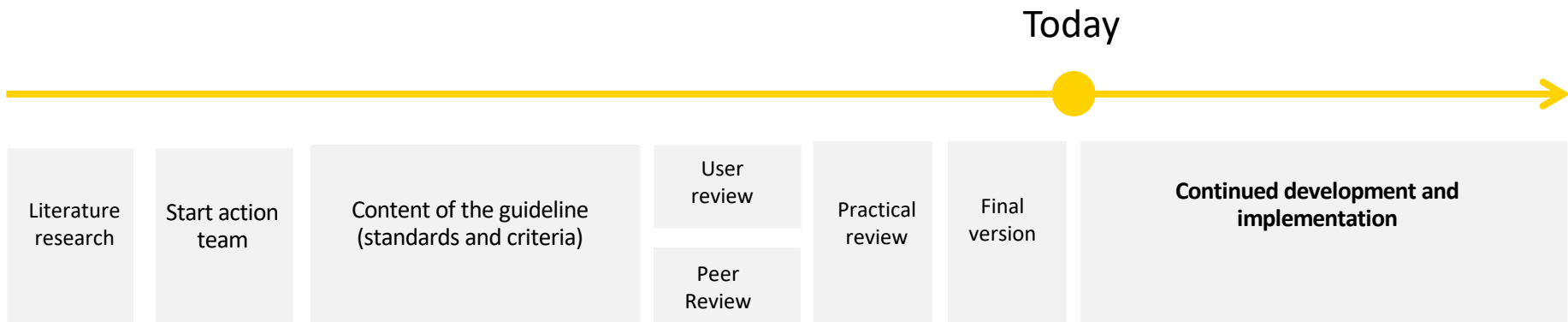
Implementation and use of the AIPA with software in daily practice

# 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.

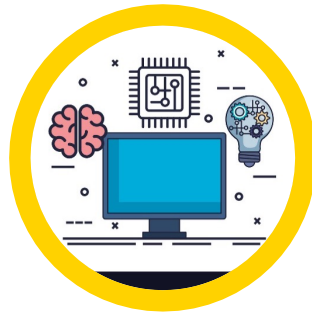


# Targeted groups



**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



**Leidraad voor kwalitatieve diagnostische en prognostische toepassingen van AI in de zorg**

Version 1.0  
21-12-2021

**Auteurs**  
Maarten van Smeden, Carl Moonen, Lotty Hooft (phase 1 through 3)  
Ilse Kant, Hine van Os, Niels Chavannes (phase 4 through 6)  
On behalf of the working party members on Medical AI

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On behalf of the working party members on Medical AI

Commissioned by the Ministry of Health, Welfare and Sport

 **Waardevolle AI**

## Welkom bij Leidraad kwaliteit AI in de zorg

Leidraad voor kwalitatieve diagnostische en prognostische toepassingen van AI in de zorg

### Waardevolle AI

Hoe beoordeel je voorspellende artificiële intelligentie (AI) algoritmen voor gezondheid en zorg op kwaliteit en effectiviteit? De Leidraad kwaliteit AI in de zorg geeft u een overzicht van de belangrijkste eisen en aanbevelingen per fase, van ontwikkeling tot implementatie. Via de [online cursus](#) komt u snel meer te weten.

De volledige Leidraad kwaliteit AI in de zorg bekijken? U kunt de pdf [hier](#) downloaden (81 pagina's). *The English version of the guideline AI in healthcare can be downloaded [here](#).*

Lees meer berichten over de leidraad op [datavoorgezondheid.nl](#)

Vragen/opmerkingen? Deze kunt u delen via de [LinkedIn-pagina](#) Leidraad kwaliteit AI in de zorg.

### Doe de online cursus (bèta)

De online leeromgeving helpt u in korte tijd op weg de leidraad beter te begrijpen en toe te kunnen passen. De modules zijn zeer toegankelijk. U kunt direct aan de slag.

Start

### Check uw kennis (bèta)

Wilt u na de online cursus of het lezen van de volledige Leidraad kwaliteit AI in de zorg kijken of u de stof hebt begrepen? Doe dan de korte toets en ontvang een certificaat als bewijs van deelname.

Start

### Voor en door het zorgveld

Een brede groep experts, vertegenwoordigers van (roepel)organisaties en betrokkenen hebben gewerkt aan de Leidraad kwaliteit AI in de zorg. In deze video een aantal van hen aan het woord.

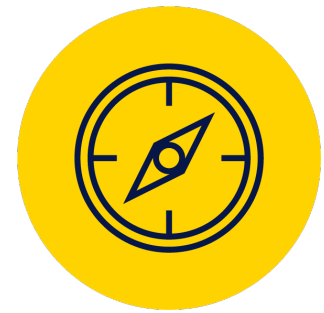
# What is the guidance?

- 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'

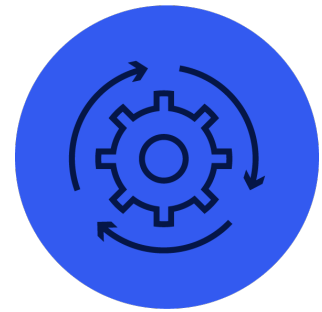
- Distinguishes between **requirements** and **recommendations**
- Requirements are indicated by:
  - ✓ **Mandatory**
  - ✓ **(strongly) recommended.**
- Use of the field standard presupposes a comply or explain approach.

# 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

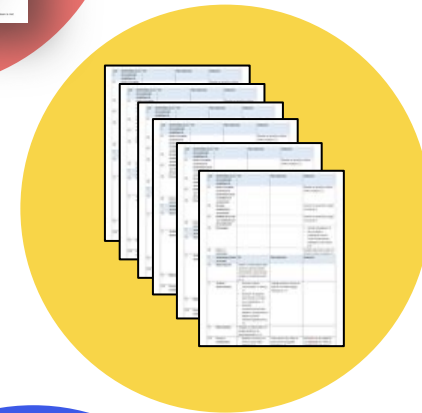
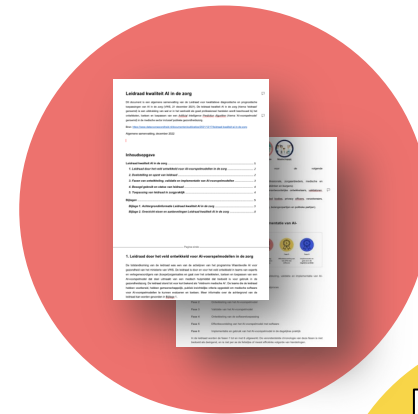
**Monitoring** on, among other things:

- Technical errors
- Incorrect use
- Unexpected side effects



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

# Implementation



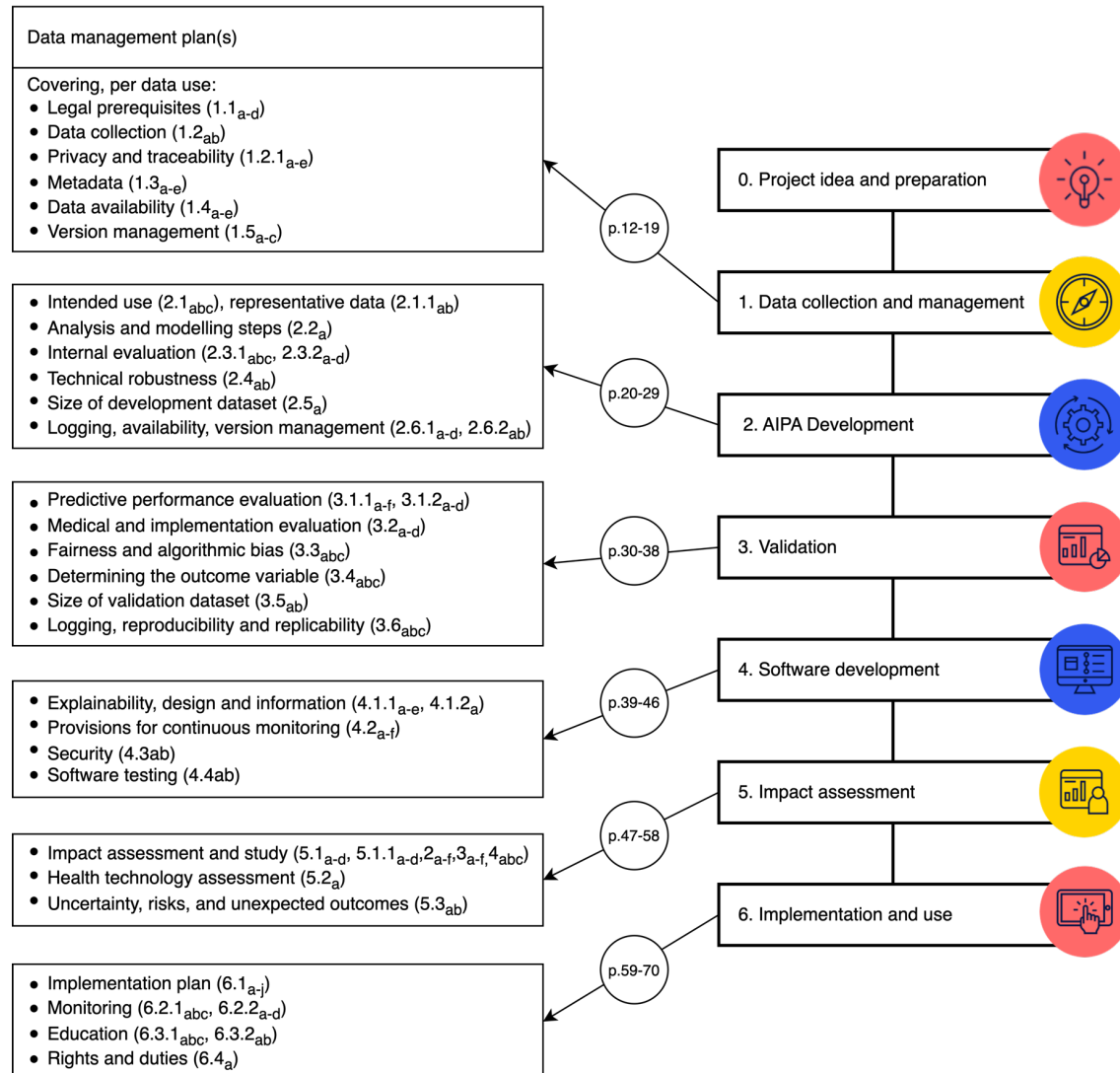
## To get started?

- 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)

[www.leidraad-ai.nl](http://www.leidraad-ai.nl)



# Contents of the guideline



# Thank you!



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