

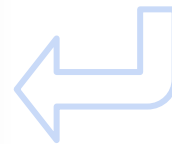
Implementatie van de Leidraad voor kwalitatieve diagnostische en prognostische toepassingen van AI in de zorg

npj | Digital Medicine www.nature.com/npjdigitalmed

REVIEW ARTICLE OPEN Check for updates

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

Anne A. H. de Hond^{1,2,3,8}, Artuur M. Leeuwenberg^{4,8}, Lotty Hooft^{4,5}, Ilse M. J. Kant^{1,2,3}, Steven W. J. Nijman⁴, Hendrikus J. A. van Os^{2,6}, Jiska J. Aardoom^{6,7}, Thomas P. A. Debray⁴, Ewoud Schuit⁴, Maarten van Smeden⁴, Johannes B. Reitsma⁴, Ewout W. Steyerberg^{2,3}, Niels H. Chavannes^{6,7} and Karel G. M. Moons⁴



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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



DOI: [10.17605/OSF.IO/TNRJZ](https://doi.org/10.17605/OSF.IO/TNRJZ)



Definitie

AIPA (AI Prediction Algorithm):

Een algoritme dat gezondheidsuitkomsten in individuen voorspelt

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Een algoritme dat gezondheidsuitkomsten in individuen voorspelt

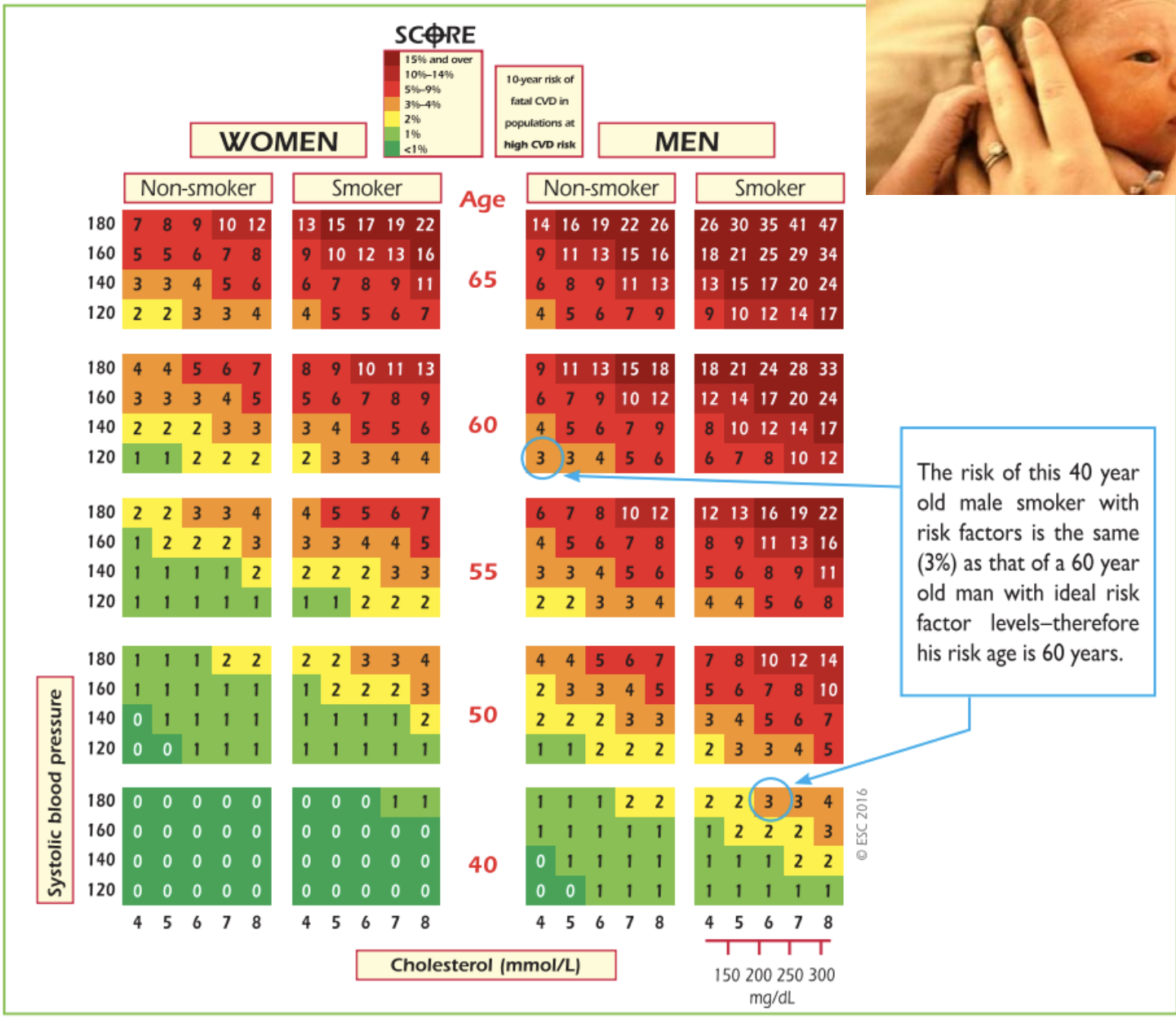
Diagnostisch = predictie van huidige status (bijv., in plaats van invasieve test)

Prognostisch = predictie van een toekomstig(e) status/event





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.

AI overall in de gezondheidszorg

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, Menecia L Black, Ellen Herschel, Tanya Simuni, Todd B Parrish, A Müller, Roger L Albin, Florian Krismer, Guangwei Du, Mechelle M Lewis, Joel S Okun, David E Vaillancourt

oa

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

Jenna Wiens^{1,19*}, Suchi Saria^{2,3,4,19}, Mark Sendak⁵, Marzyeh Ghassemi^{6,7,8}, Vincent X. Liu⁹, Finale Doshi-Velez¹⁰, Kenneth Jung¹¹, Katherine Heller^{12,13}, David Kale¹⁴, Mohammed Saeed¹⁵, Pilar N. Ossorio¹⁶, Sonoo Thadaney-Israni¹⁷ and Anna Goldenberg^{6,8,18,19*}

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: Murdo MacLeod/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

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

ORIGINAL REPORT

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

The NEW ENGLAND JOURNAL of MEDICINE

View
Reprints

REVIEW ARTICLE

Jeffrey M. Drazen, M.D., Editor;
Isaac S. Kohane, M.D., Ph.D., and Tze-Yun Leong, Ph.D., Guest Editors

AI IN MEDICINE

Artificial Intelligence and Machine Learning in Clinical Medicine, 2023

Charlotte J. Haug, M.D., Ph.D., and Jeffrey M. Drazen, M.D.

Lehtonen, PhD¹; Piao

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



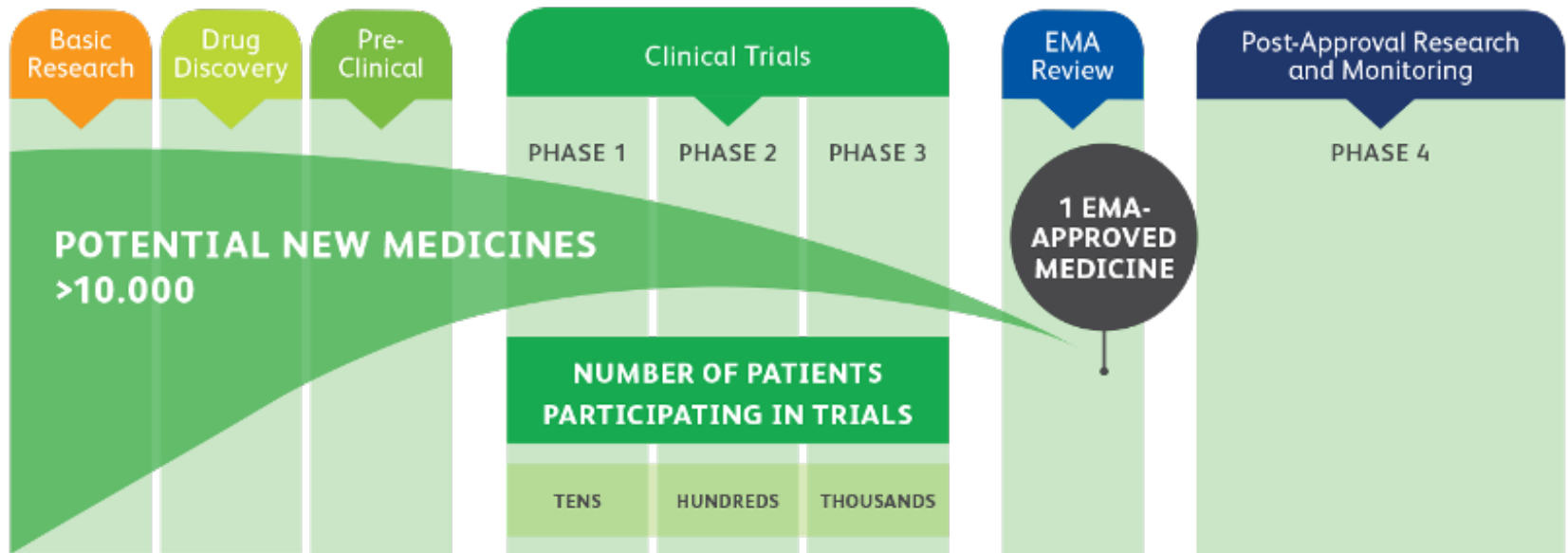
Chad J. Zack, MD, MS,^{a,*} Conor Senecal, MD,^{b,*} Yaron Kinar, PhD,^c Yaakov Metzger, MD, PhD,^c Yoav Bar-Sinai, MS,^c R. Jay Widmer, MD, PhD,^d Ryan Lennon, MS,^d Mandeep Singh, MD, MPH,^d Malcolm R. Bell, MD,^d Amir Lerman, MD,^b Rajiv Gulati, MD, PhD^d



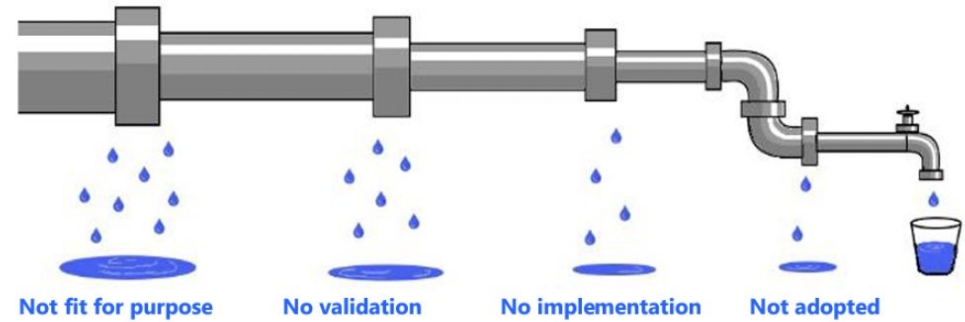
Wat verwacht u van een AIPA in termen van **kwaliteit**?



Het ontwikkelingspad voor geneesmiddelen



Is niet het pad van AIPAs



Voor AIPAs (vaak klasse II_a of II_b):

CE approval (door een notified body) = **market access**



Landschap van (enkele) relevante documenten

The European Union Medical Device Regulation
Regulation (EU) 2017/745 (EU MDR)

Document 02017R0745-20200424

Consolidated text: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance) (Text with EEA relevance)

Access initial legal act (in force) Access current version (11/03/2020)

ELI: <http://data.europa.eu/eli/reg/2017/745/2020-04-24>

Languages and formats available

Multilingual display

Text

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance) (OJ L 117 5.4.2017 p. 1)

Regelgeving

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AIPA Kwaliteit (een consensus document)

Ministerie van Volksgezondheid, Welzijn en Sport

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Innovation Funnel for Valuable AI in Healthcare

In order to help researchers and developers in the process from development to scaling up valuable artificial intelligence (AI), this tool offers clues in the scope for action within the laws and regulations. For example, it is possible to start preparing early for requested minimum requirements or standards. And reflect on actions to achieve human-centered and reliable AI applications.

Download 'Innovation Funnel for Valuable AI in Healthcare'

PDF document | 27 pagina's | 1,3 MB
Publicatie | 09-01-2022

This tool supports the innovation process in five domains (value, application, ethics, technology, responsibility). The bundling in an innovation funnel helps to create as much value as possible: each phase offers room to work creatively and iteratively, but has a well-defined goal in the process and is based on a substantiated use of resources.

[Dutch version: Hulpmiddel Handelinstrument Waardevolle AI voor gezondheid](#)

AIPA Ontwikkelingsproces (een innovatiegids)

Stappenplan Healthy AI (HAI)
Een stappenplan voor de kwaliteit van AI-software

Sade Faneyte, klinisch informaticus
versie 1.1

SMPE/e TU/e Eindhoven University of Technology MAASSTAD ZIEKENHUIS

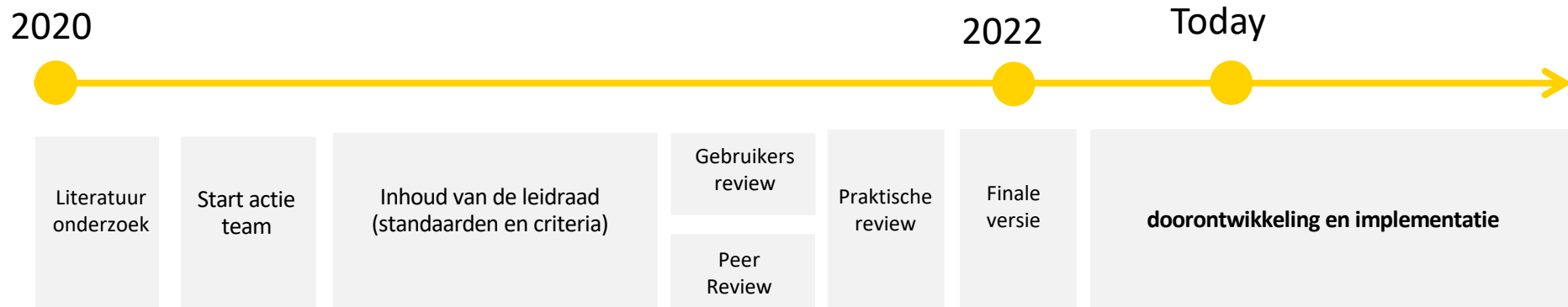
Stappenplan Healthy-AI Aanschaf AI-gebaseerde medische hulpmiddelen



De ontwikkeling van de leidraad

Doel: Gezamenlijk! Creëren van een standaard die
✓ **Breed toepasbaar** is in de gezondheidszorg.

Talrijke werkgroepbijeenkomsten met experts (vanuit alle stakeholders) om per fase de belangrijkste onderwerpen te bepalen en te prioriteren en de **kwaliteitsnormen** te beschrijven.



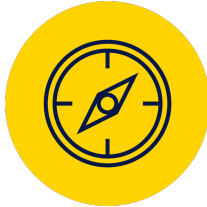
Scope van de Leidraad AI

kwaliteit van ontwikkeling tot implementatie



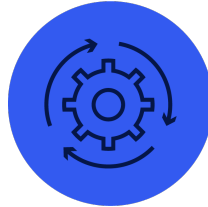
Fase 0

Project idee en
voorbereiding



Fase 1

Collectie en
management van
de data



Fase 2

Ontwikkeling van
de AIPA



Fase 3

Validatie van de
AIPA



Fase 4

Ontwikkeling van
de benodigde
software



Fase 5

Impact
assessment van de
AIPA in
combinatie met
de software

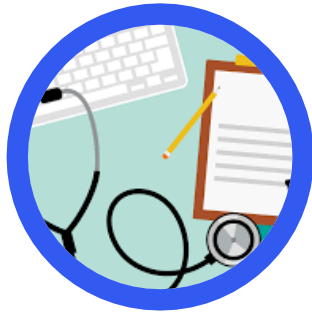


Fase 6

Implementatie en
gebruik van de
AIPA met software
in de dagelijkse
praktijk

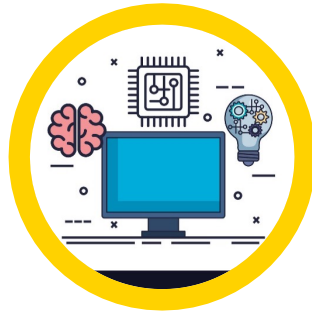


Doelgroepen



Toepassen van AI

Zorgverleners
Professioneel
Wetenschappelijk
Medische verenigingen
Educatie/training
IT leveranciers
Patiënten / Burgers



Ontwikkeling van AI

Validatoren
Ontwikkelaars
Onderzoekers
Datamanagers
Data leveranciers



Evalueren van AI

Kwaliteitsmedewerkers
Notified bodies
Peer reviewers
Privacy officers
Zorgverzekeraars



Maatschappelijk

Patiënt(en)-(verenigingen)
Belanghebbende partijen
Politieke partijen
Geïnteresseerde burgers



Wat is de guidance?

- Wat de zorgsector beschouwt als **goed professioneel handelen** in de ontwikkeling, evaluatie en implementatie van een AIPA
- Startpunt: beschikbare kennis en wetenschappelijke review
- Leidraad is niet wettelijk bindend

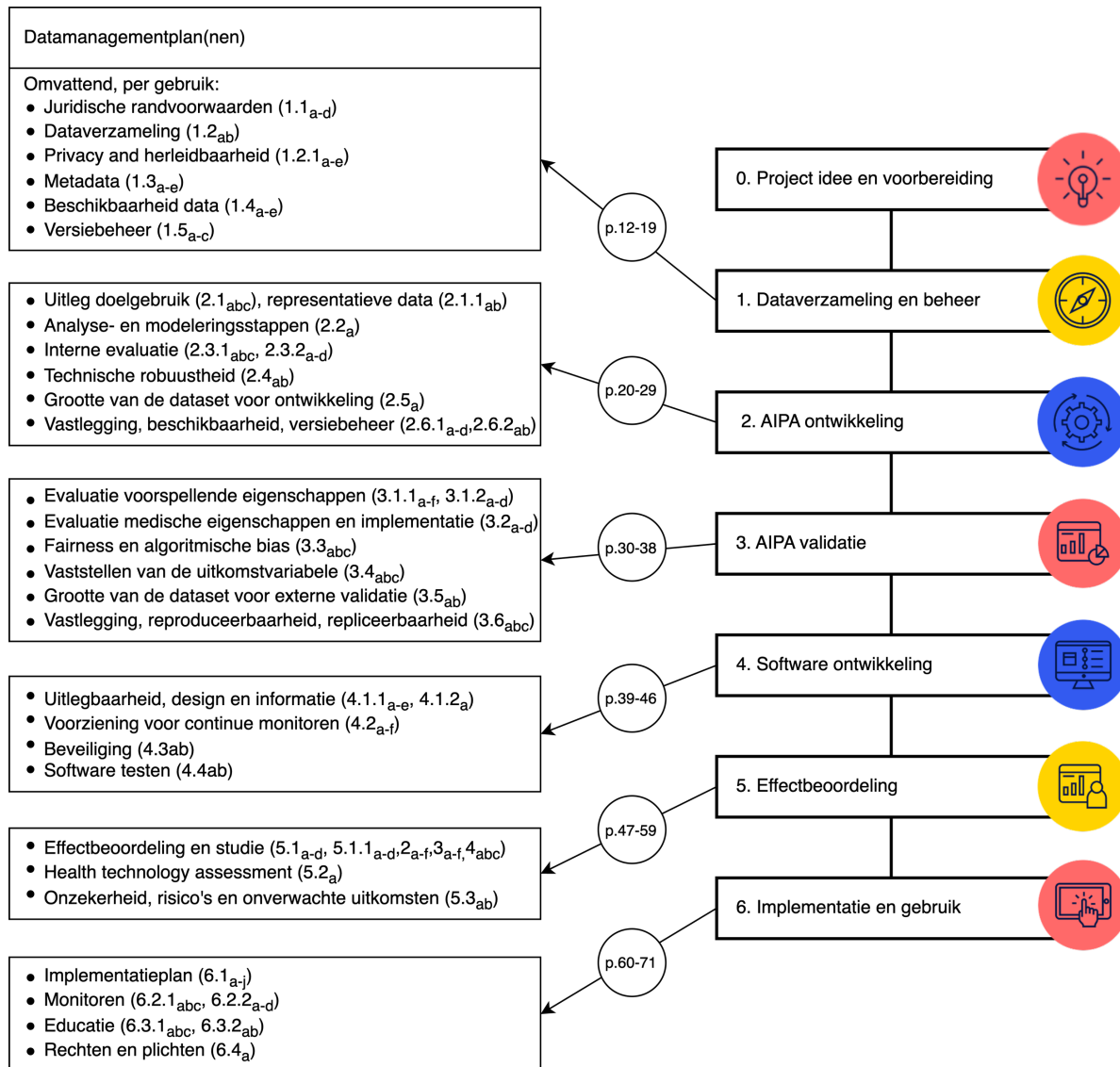


‘Comply or explain’

- Maakt onderscheid tussen **eisen** en **aanbevelingen**
- Worden aangegeven met:
 - ✓ **Moet**
 - ✓ **(sterk) aanbevolen.**
- Het gebruik van de leidraad veronderstelt een pas toe of leg uitbenadering.



Inhoud van de leidraad



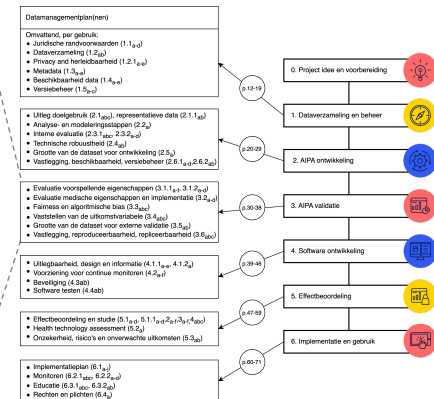
Fase 3 Validatie

p. 30-38

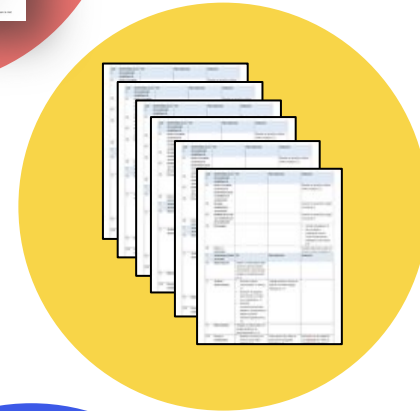
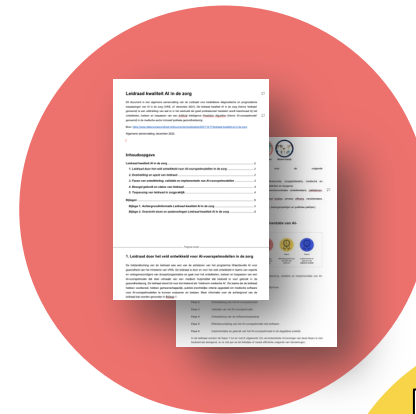
Externe validatie: **evaluatie van predicties** (in data ongebruikt tijdens ontwikkeling)

- Onderscheid in evaluatie:
 - Statistische eigenschappen
 - Klinische eigenschappen
 - Fairness en algorithmic bias

- Geen minimum eisen voor predictieve performance (contextafhankelijk)



Materialen



Om te beginnen

- De leidraad
- Een korte online cursus
- Tabel met aanbevelingen per fase
- Overzicht van belangrijke aspecten per fase
- Vier-pagina samenvatting
- Een samenvatting voor patiënten(vertegenwoordigers)
- Overzicht van samenhang bestaande wet en regelgeving

www.leidraad-ai.nl



DOI: 10.17605/OSF.IO/TNRJZ

Implementatie leidraad

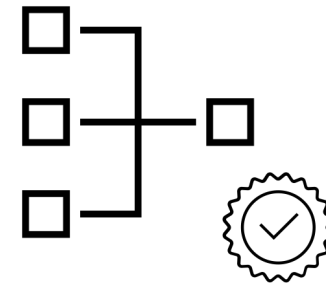
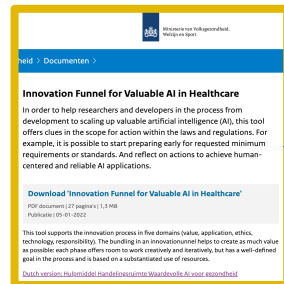


AI kwaliteitsmanagementsysteem

AIPA leidraad



AIPA innovatie
funnel



Bedankt!



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