AI in de Zorg

Normalisatie van AI in de Zorg

Zorg & ICT beurs, 9-10-11 april 2024

De waarde van normen

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De waarde van normen

Inhoudsopgave

- Introductie NEN
- NEN en AI in de Zorg
- Wat speelt er (internationaal) rondom AI?
  - AI Act
  - Generiek
    - CEN JTC 21
    - ISO SC 42
  - Zorg specifiek
    - IEC TC 62
    - ISO TC 215
- Afronding

Introductie NEN

- Wat zijn Normen?
  - Wie gebruikt normen?
  - Wie heeft aan normen geschreven?

- NEN/NEC – CEN/CENELEC – ISO/IEC

1. Transparant
2. All parties concerned
3. Consensus

> Wat doet NEN?

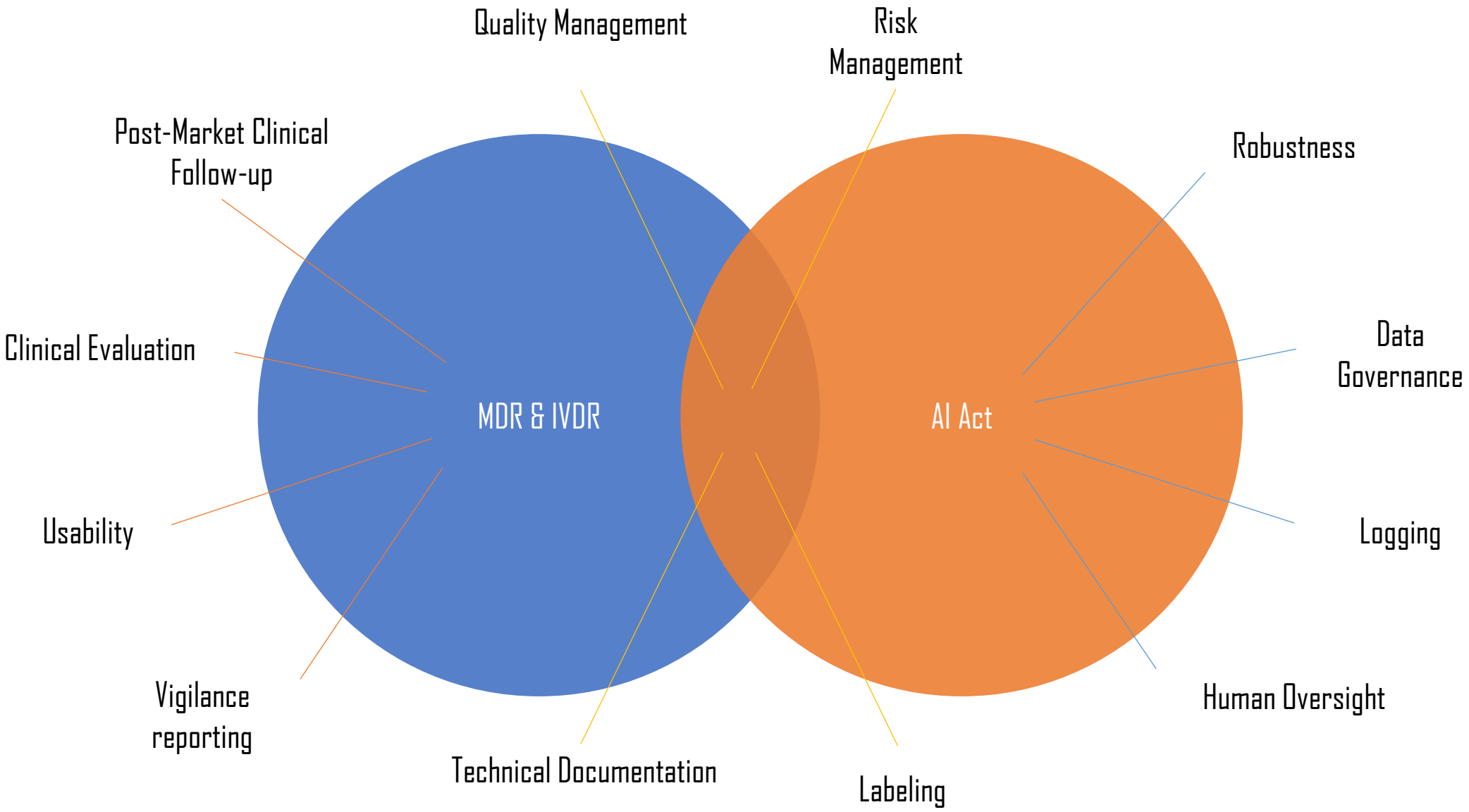
Stichting Koninklijk Nederlands Normalisatie Instituut (NEN) brengt partijen, zoals bedrijfsleven, overheden en branche-organisaties bij elkaar om afspraken te maken en deze vast te leggen in normen of richtlijnen. Zo zorgen we samen voor een maatschappij die duurzamer, veiliger of efficiënter is.

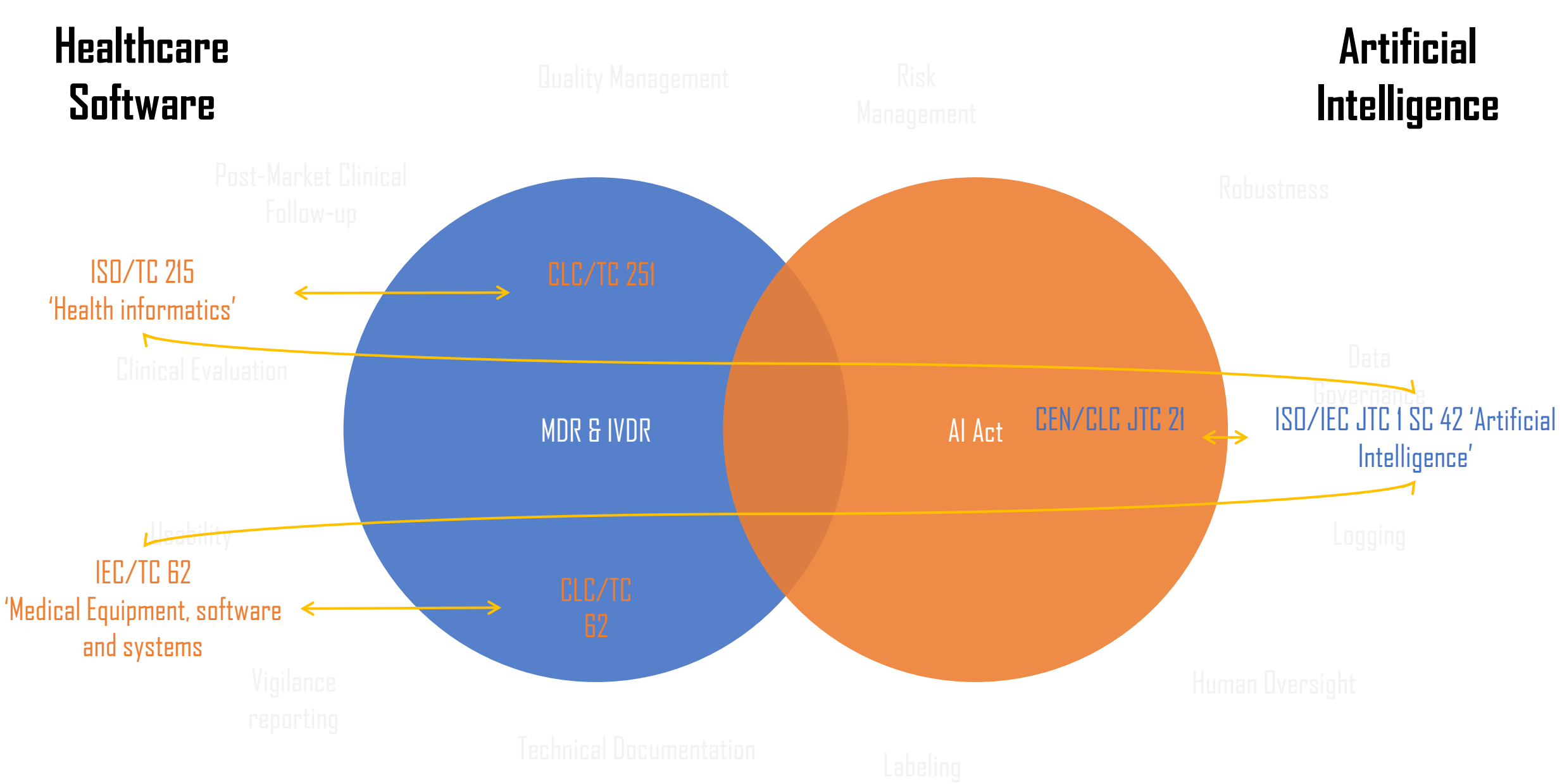
NEN en AI in de Zorg

- NC AI en Big Data (381420)
  - Werkgroep 1: Advisory Group
  - Werkgroep 2: AI en Medische Hulpmiddelen

Wat speelt er (internationaal) rondom AI?

- **AI Act**
  - Journal publication : June 2024 - Expected
  - Coming into force : June 2024 - 20 days after publication)
  - Date of application : June 2026 - 2 years for Annex III and others, 3 years for Annex I (MD & IVD)
- **Generic**
  - European Union : CEN/CENELEC JTC 21 – ‘Artificial Intelligence’
  - Global : ISO/IEC JTC 1 / SC 42 – ‘Artificial Intelligence’
- **Healthcare specific**
  - Global : IEC TC 62 – ‘Medical Equipment, Software, and Systems’
  - Global : ISO TC 215 – ‘Health Informatics’


Quality Management
Risk Management
Post-Market Clinical Follow-up
Robustness
Clinical Evaluation
Data Governance
MDR & IVDR
AI Act
Usability
Logging
Vigilance reporting
Human Oversight
Technical Documentation
Labeling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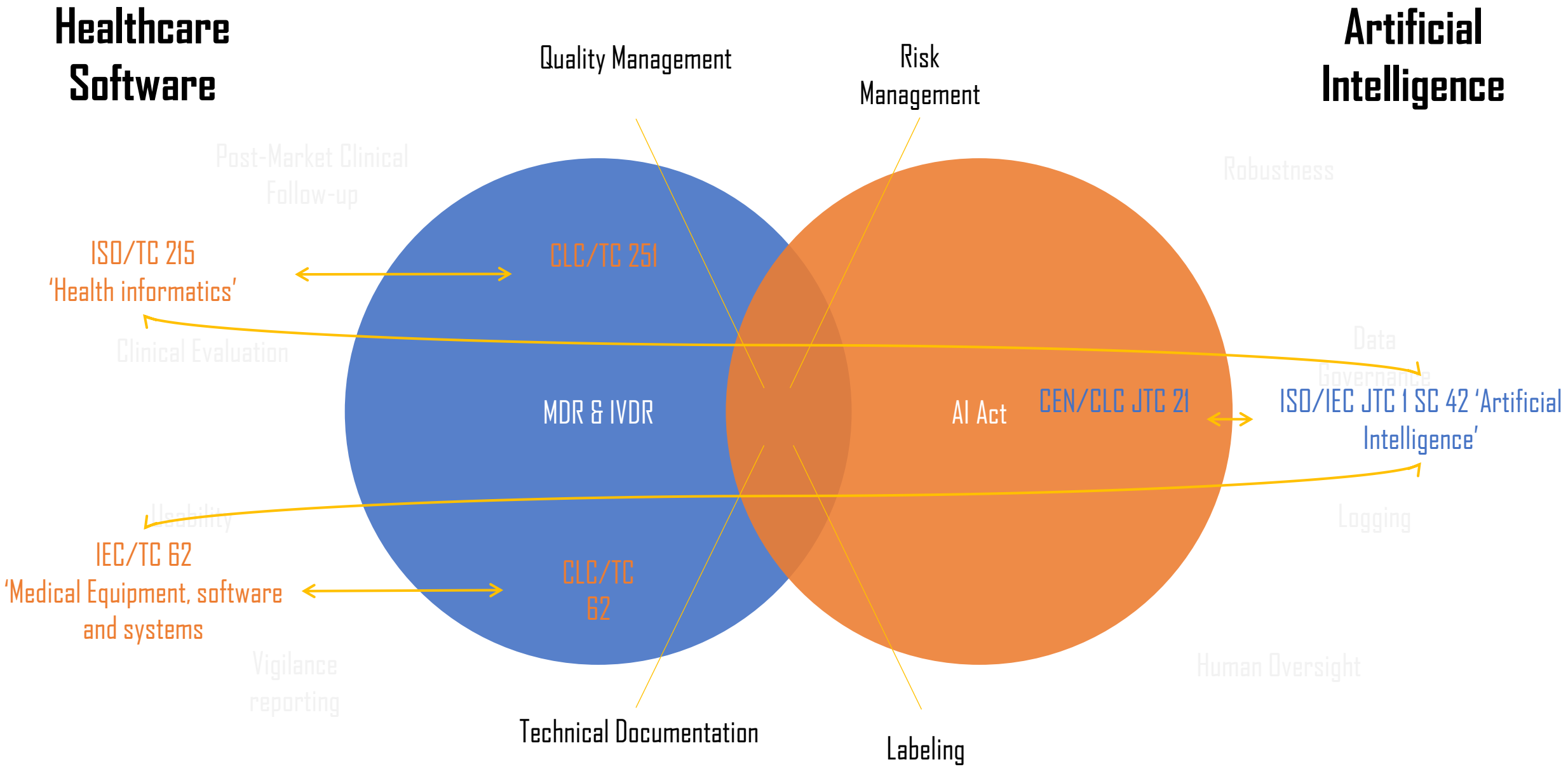
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Standardisation Request

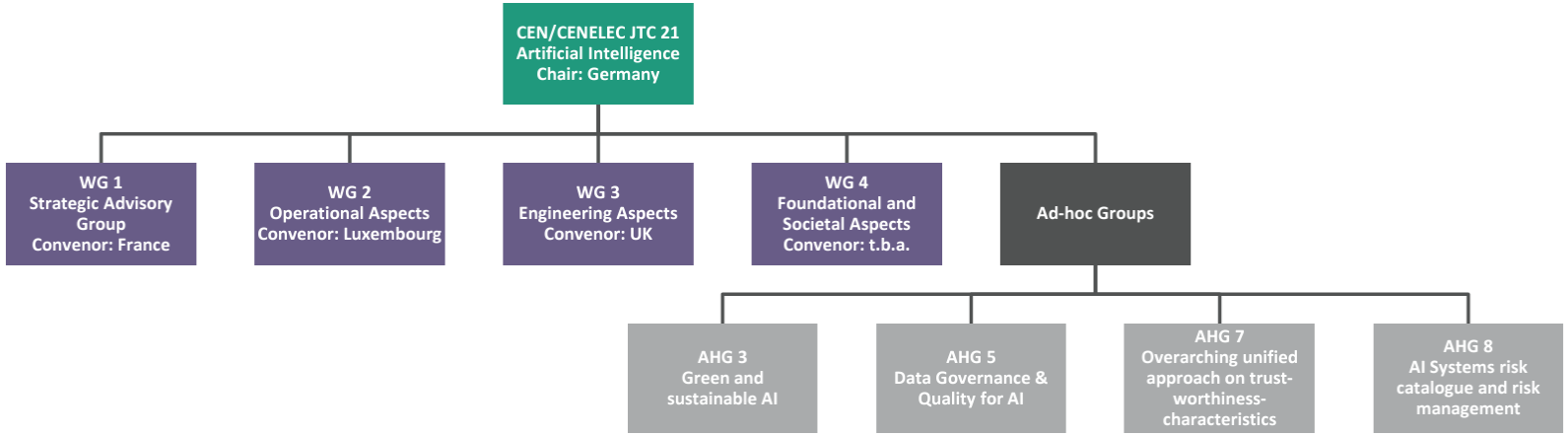
- Er is een ‘standardisation request’ over AI vanuit de Europese Commissie (M/593)
  - Vraagt om beschikbaarheid ‘harmoniseerbare’ normen per **30 April 2025**
  - ‘*presumption of conformity*’ voor een Europese Richtlijn (artikel 40)
  - Pending: additioneel standardisation request rondom:
    ‘*energy & other resource consumption of AI systems during its lifecycle*’

Risk Management systems	Accuracy specifications
Governance & quality of datasets used to build AI systems	Robustness specifications
Record keeping through logging capabilities	Cybersecurity specifications
Transparency and information provisions for users	Quality management systems for providers of AI systems, including post-market monitoring processes
Human oversight	Conformity assessment

CEN/CENELEC JTC 21 ‘Artificial Intelligence’

- Neemt (1) internationale standaarden over zoals van ISO/IEC JTC 1 / SC 42 en (2) produceert normen die de Europese markt en maatschappij aangaan

- Werkt momenteel onder andere aan:
  - TR 17894 – AI Conformity Assessment
  - prEN ISO/IEC 42001 – Management System (in huidige vorm waarschijnlijk niet acceptabel voor harmonisatie)
  - prEN XXXXX – AI Risk Management
  - prEN XXXXX – AI tasks and evaluation methods of computer vision systems
  - prEN XXXXX – AI Trustworthiness framework



Artikel 40 – AI Act

Artikel 40 vraagt om:

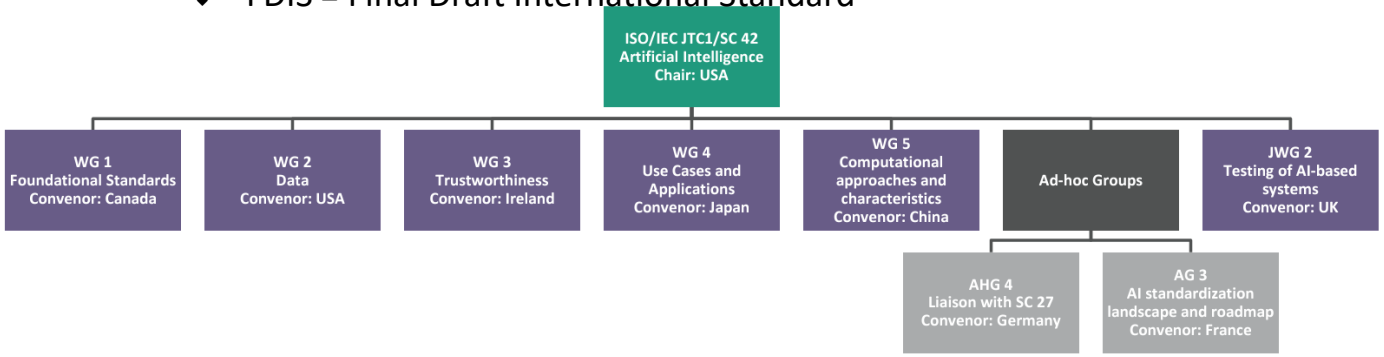
- Normen die: ‘clear’ & ‘consistent’ zijn met de bestaande standaarden in sectoren, zoals de MDR & IVDR
  - Note: JTC 21 heeft minimale vertegenwoordiging uit de Medisch Hulpmiddelen en In-Vitro Diagnostische Medisch Hulpmiddelen industrieen, en geen vertegenwoordiging uit de zorg
- Als er geen normen beschikbaar zijn per 30 April 2025, kan de EU Commissie besluiten om:
  - Deadline uit te stellen tot latere datum (note: Annex III hoog risico producten dienen per 26 juni 2026 CE markering te hebben), of
  - Per **Artikel 41** ‘Common Specifications’ te publiceren onder de noemer van ‘Implementing Acts’

ISO/IEC JTC 1 / SC 42

- **ISO/IEC JTC 1 / SC 42 – Artificial Intelligence**
  - JTC 1 – Information Technology met Subcommittee 42 – AI

- **Scope**
  - Standardization in the area of Artificial Intelligence
    - Serve as the focus and proponent for JTC 1's standardization program on Artificial Intelligence
    - Provide guidance to JTC 1, IEC, and ISO committees developing Artificial Intelligence applications

  - **Onder andere:**
    - Data quality for analytics and machine learning (FDIS 5259-1 through 6)
    - Treatment of unwanted bias in classification and regression machine learning tasks (TS 12791)
    - Controllability of automated artificial intelligence systems (TS 8200)
    - Application of AI technologies in health informatics (AWI TR 18988)
      - AWI = Approved Work Item
      - TS = Technical Specification (in Nederland bekend als een NPR)
      - FDIS = Final Draft International Standard



IEC TC 62

- Vision: To make medical software as safe as medical electrical equipment already is.

- Onderverdeeld in 4 subcommittees:
  - 62A – Common aspects of medical equipment, software and systems
  - 62B – Medical imaging equipment, software and systems
  - 62C – Medical equipment, software and systems for radiotherapy, nuclear medicine and radiation dosimetry
  - 62D – Particular medical equipment, software and systems.

Strategy:

1. Assess current acceptability of standards, and determine the need to update
2. Provide input to all authors of AI/ML-related standards
3. Write new software-related standards where necessary
4. Help standard writers to keep standards which are developed in parallel consistent

IEC TC 62

AI-related standards currently in the TC62s work program:

ISO 24971-2 ED1 Medical devices – Guidance on the application of ISO 14971 - Part 2: Machine learning in artificial intelligence

Guidance to ISO 14971 regarding the application for AI/ML Medical Devices

IEC 63450 ED1 Testing of Artificial Intelligence / Machine Learning-enabled Medical Devices

Inspired by ISO/IEC 29119-11

IEC 63524 ED1 Artificial Intelligence enabled Medical Devices — Computer assisted analysis software for pulmonary images - Algorithm performance test methods

Outline based on YY/T 1858-2022 (Artificial intelligence medical device—Computer assisted analysis software for pulmonary images—Algorithm performance test methods)

IEC 62521 ED1 Machine Learning-enabled Medical Device – Performance Evaluation Process

Aligned with FDA guidance for the clinical evaluation of Software as a medical device and Guidance on clinical evaluation (MDR) / Performance evaluation (IVDR) of medical device software MDCG 2020-1

*= Note: Dit zijn ‘globale’ standaarden en passen niet per se onder de AI Act

ISO TC 215

- ISO/TR 24291:2021 – Health Informatics – Applications of machine learning technologies in imaging and other medical applications
- Data georiënteerd

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Afronding

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Meepraten? Neem contact op met NEN!