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Voices from outside

- legal compliance

Workshop Centre for AI in Health, AAU



FROM ANALYSING EXISTING DATA TO OBSERVING, INFERRING, PREDICTING AND ACTING

AI in healthcare is changing character



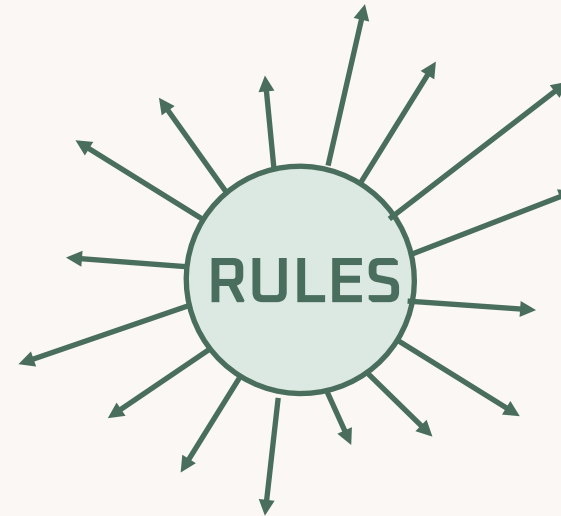
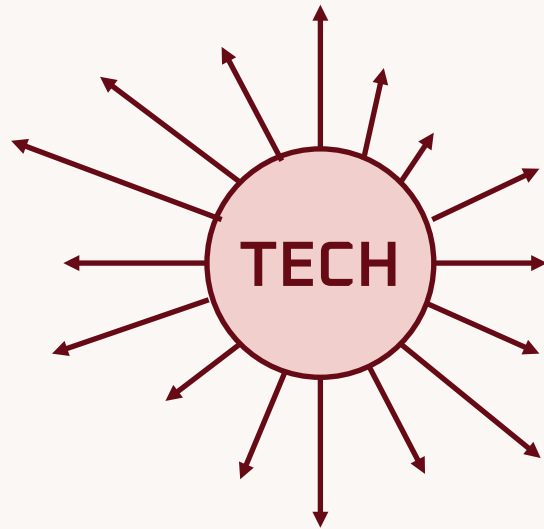
The research object may be a system that senses, learns, predicts and intervenes – no longer just a model





TECHNICAL COMPLEXITY

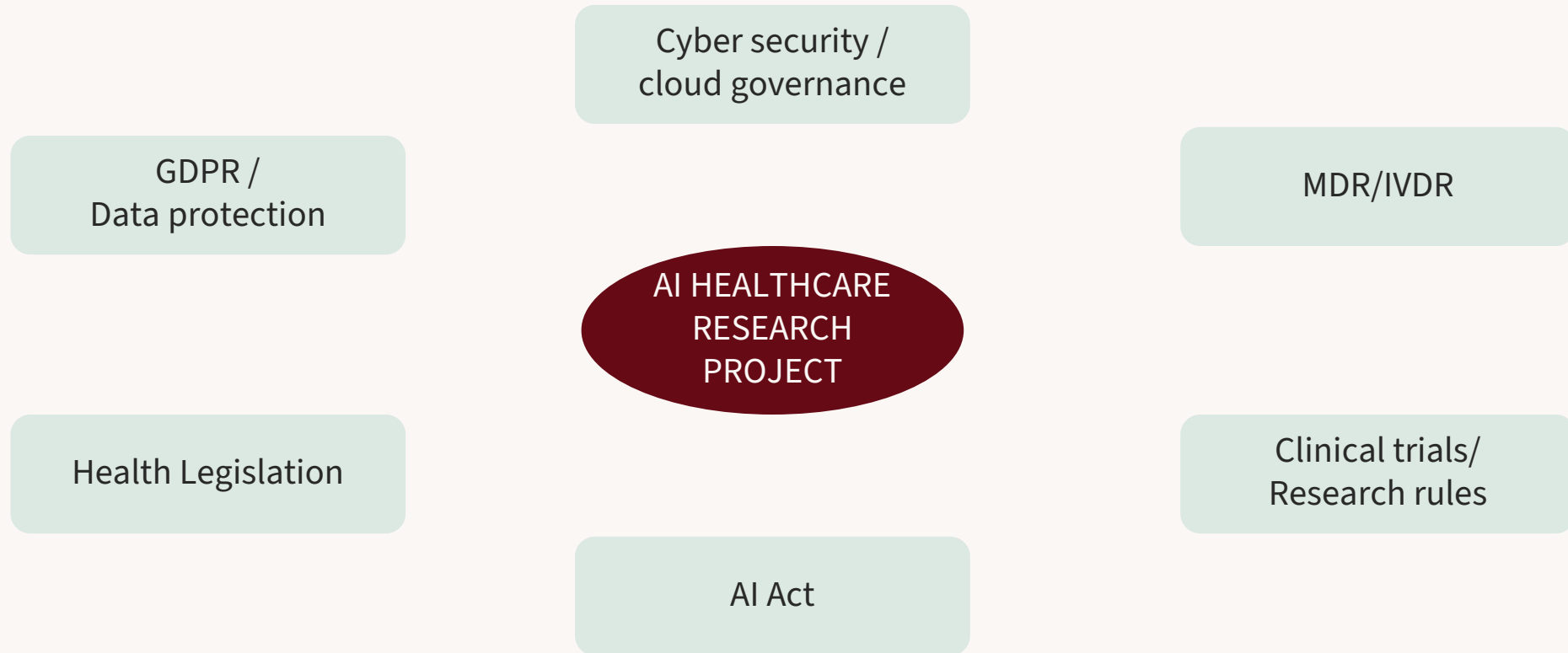
Legal complexity





THERE IS NO SINGLE “AI LAW” FOR HEALTHCARE RESEARCH

One AI project → Many legal frameworks

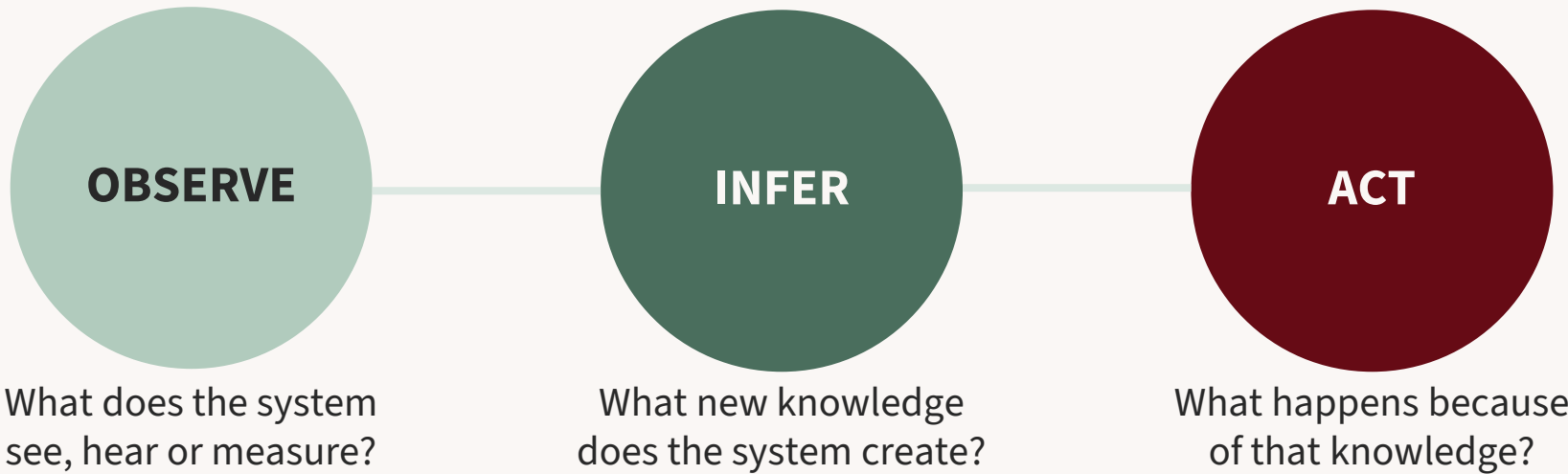


The same project can change legal character as it moved from research → validation → clinical deployment



THE DECISIVE QUESTIONS ARE WHAT THE SYSTEM OBSERVES, INFERS AND DOES

The legal issue is no longer only “the data”



Example: Wearable sensors → movement + sleep + pulse → deterioration risk → alert or treatment adjustment

A central research question: At which point did the research project create a new health data point?



MORE DATA, MORE KNOWLEDGE, MORE AUTONOMY

Seven developments - one pattern



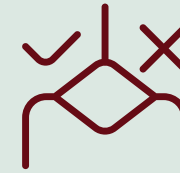
MORE DATA

- AI diagnostics
- Multimodal AI
- Ambient clinical AI
- Continuous monitoring



MORE KNOWLEDGE

- Digital biomakers
- Risk scores
- Digital twins
- Simulated futures



MORE AUTONOMY

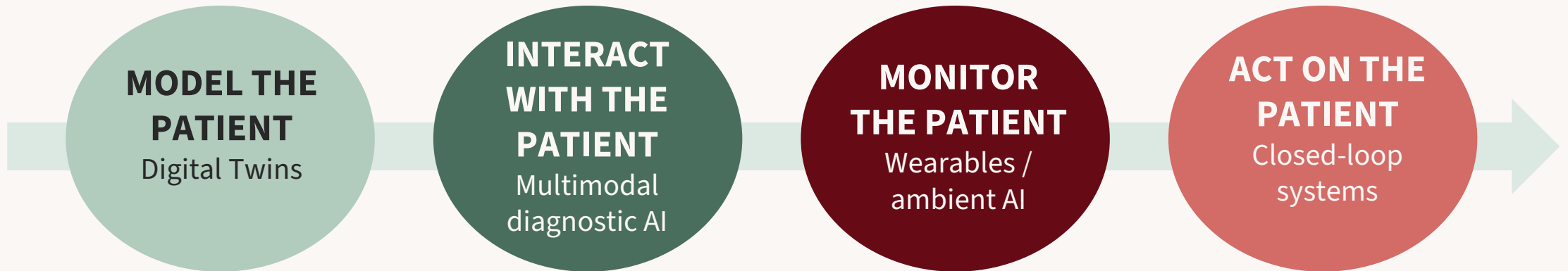
- Agentic systems
- Clinical decisions support
- Closed-loop treatment
- Automated alerts

Pattern matters legally – each step expands what the system knows or can do in relation to the person



HEALTHCARE AI: FROM ANALYSING DATA TO MODELLING, INTERACTING WITH, MONITORING AND ACTING ON PATIENTS

From AI tool to AI actor



**The legal question is no longer only what data AI processes –
but what role we allow AI to assume in healthcare**



NOT JUST “CAN WE USE HEALTH DATA?” - BUT WHAT NEW DATA DOES THE SYSTEM CREATE?

The difficult GDPR questions have changed

1

WHAT IS PERSONAL DATA?

Inputs, features, inferences and predictions

2

WHAT IS NECESSARY?

Do we need all modalities, full history and continuous observation?

3

WHAT IS THE PURPOSE?

Secondary use of records, images, biobanks and historical datasets?

4

WHO PROCESSES?

Hospital, university, cloud provider, model provider and sub-processors?

ECG + movement + voice → features → AI inferens → ”risk of neurological deterioration”

At which point did the research project create a new health data point?



THE ROUTE FROM RESEARCH PROTOTYPE TO HEALTHCARE SYSTEM CHANGES THE LEGAL QUESTION

AI Act + healthcare: classification is everything



③ questions to ask early:

- What is the intended use?
- Is it part of, or itself, a regulated medical device?
- Who is the provider – and who is the deployer?

CLOSING QUESTION

Are we still designing a research project –
or already designing a healthcare
system?

Good AI research in healthcare increasingly requires regulatory competences at the design stage



LET'S STAY IN TOUCH

CONTACT



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