

Data Ethics & Legislation

ChatMED Project



The 2026 Regulatory Landscape

Three major frameworks govern our work in medical AI:

GDPR

Strict rules on processing personal and health data

EU AI Act

Comprehensive regulation based on risk classification

EHDS

European Health Data Space – secure cross-border health data sharing



EU AI Act: Risk Categories

Minimal / Limited Risk

Transparency obligations only – e.g., general chatbots

High Risk

Strict compliance, risk management, human oversight – e.g., medical devices

Unacceptable Risk

Banned outright

Healthcare AI tools fall almost entirely into the **High Risk** category, requiring rigorous conformity assessments.





GDPR Fundamentals



1

Article 5

Principles of processing:
minimization and accuracy

2

Article 9

Health data is a "**special category**" requiring explicit consent

3

Article 22

Rights against purely automated decision-making



Core Data Ethics in AI



Fairness

Avoiding bias in training data – biased data produces biased medical advice



Accountability

Defining who is responsible when the AI is wrong



Transparency

Making AI decisions explainable – no black boxes in medicine



Applying Legislation to ChatMED Use Cases

USE CASE 1

HomeDOctor

Public health chatbot for symptom assessment and OTC recommendations

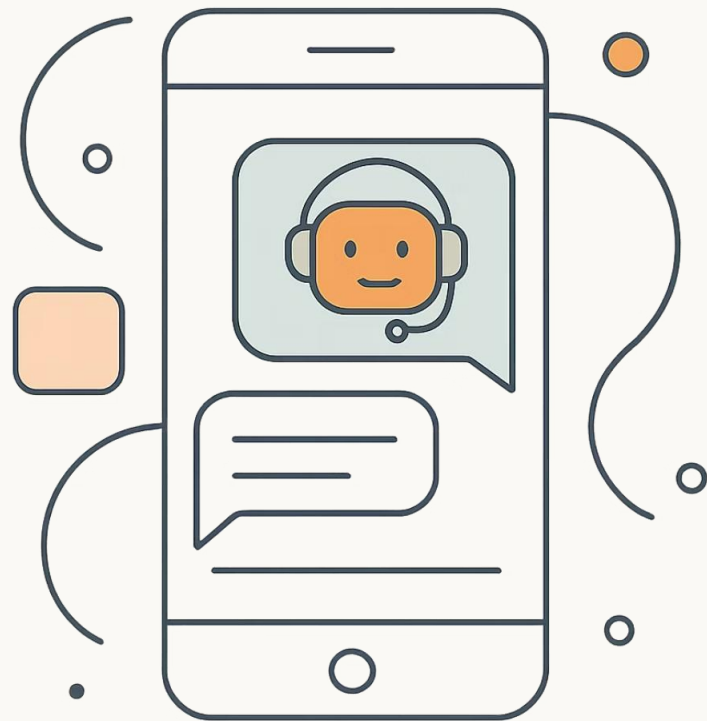
USE CASE 2

Neurology AI Orchestrator

Clinical assistant supporting neurologists with differential diagnosis



HomeDOCTOR: AI Act & Transparency



Role

Symptom
assessment and
OTC
recommendations
for the public

Key Requirement


Users must explicitly
know they are
interacting with an
AI, not a human
doctor

Critical Boundary

Providing
information vs.
practicing medicine



HomeDOctor: Fairness & Non-Discrimination

 Ethical Challenge: HomeDOctor is tailored to the Slovenian health system – but what about tourists and non-citizens?

The Problem

Local OTC advice may not apply to non-citizens or visitors

The Obligation

EU AI Act and basic ethics require non-discrimination

The Solution

Route critical queries to universal urgent care – available to everyone



HomeDOctor: GDPR & Data Minimization

Local Hosting

No data leaves the controlled environment

No Retention

Conversations are ephemeral – deleted after each session

Privacy by Design

No PII collected – major GDPR risks eliminated by default





Neurology AI Orchestrator: High-Risk Classification

1

Role

Assists neurologists with differential diagnosis and missed details

2

Classification

High Risk under the EU AI Act

3

Requirement

Human-in-the-Loop (HITL) – the neurologist makes the final call

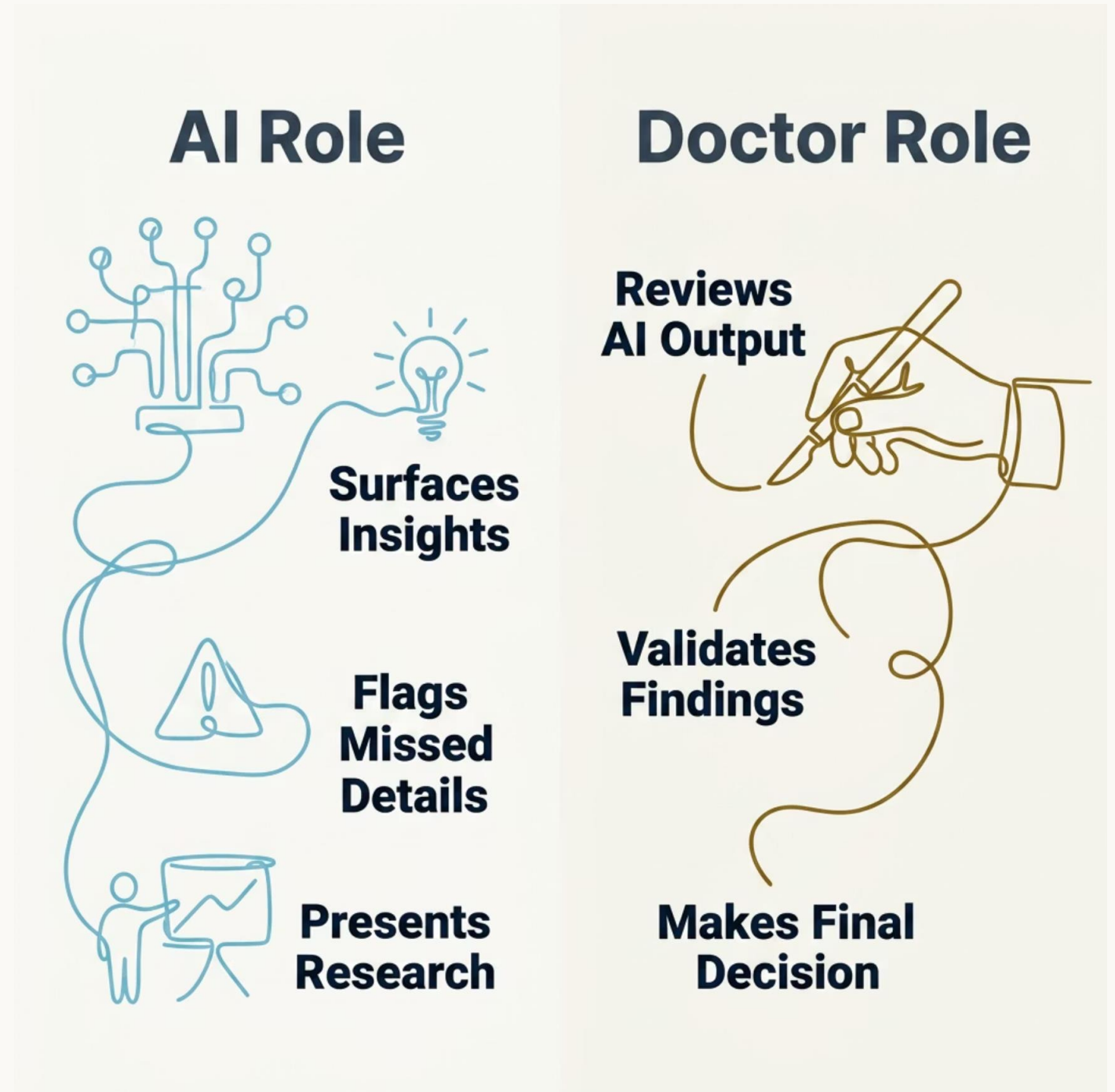


Orchestrator: Avoiding Automated Decisions



 GDPR Article 22 prohibits AI from independently deciding a patient's treatment plan.

The Orchestrator must **surface insights** for the human doctor to review and validate – never act as the decision-maker.





Collecting Data for Future Models: The Dilemma

The Need

AI models require vast, quality data to improve accuracy

The Law

GDPR data minimization restricts what we can retain

The Challenge

How do we legally build a custom dataset from ChatMED interactions?





Legal Bases for Data Collection



Key Requirement

Both paths converge on the same safeguard: data must be **irreversibly anonymized** before entering any training set.

- 📄 The research exemption under Article 89 is available but demands rigorous anonymization protocols.



What Is Allowed vs. Not Allowed

✓ Allowed

- Training on anonymized, diverse clinical records
- Triage recommendations with human oversight

✗ Not Allowed

- AI making final diagnostic decisions without a doctor
- Training on identifiable patient data without explicit consent



Conclusion: Ethics by Design

Ethics and legislation aren't hurdles – they are the blueprint for building trustworthy medical AI.



Build Compliance In

Integrate regulatory requirements into the architecture from day one



Prioritize Transparency

Explainable AI decisions at every layer of the system



Human Oversight Always

Fairness and human control are non-negotiable in medical AI

