HEADLINER
Machine Learning and Generative AI in Medical Devices

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zühlke
empowering ideas

Machine Learning and Generative AI in Medical Devices

Intelligent Health 2023

Dr. Lisa Falco & Dr. Gabriel Krummenacher

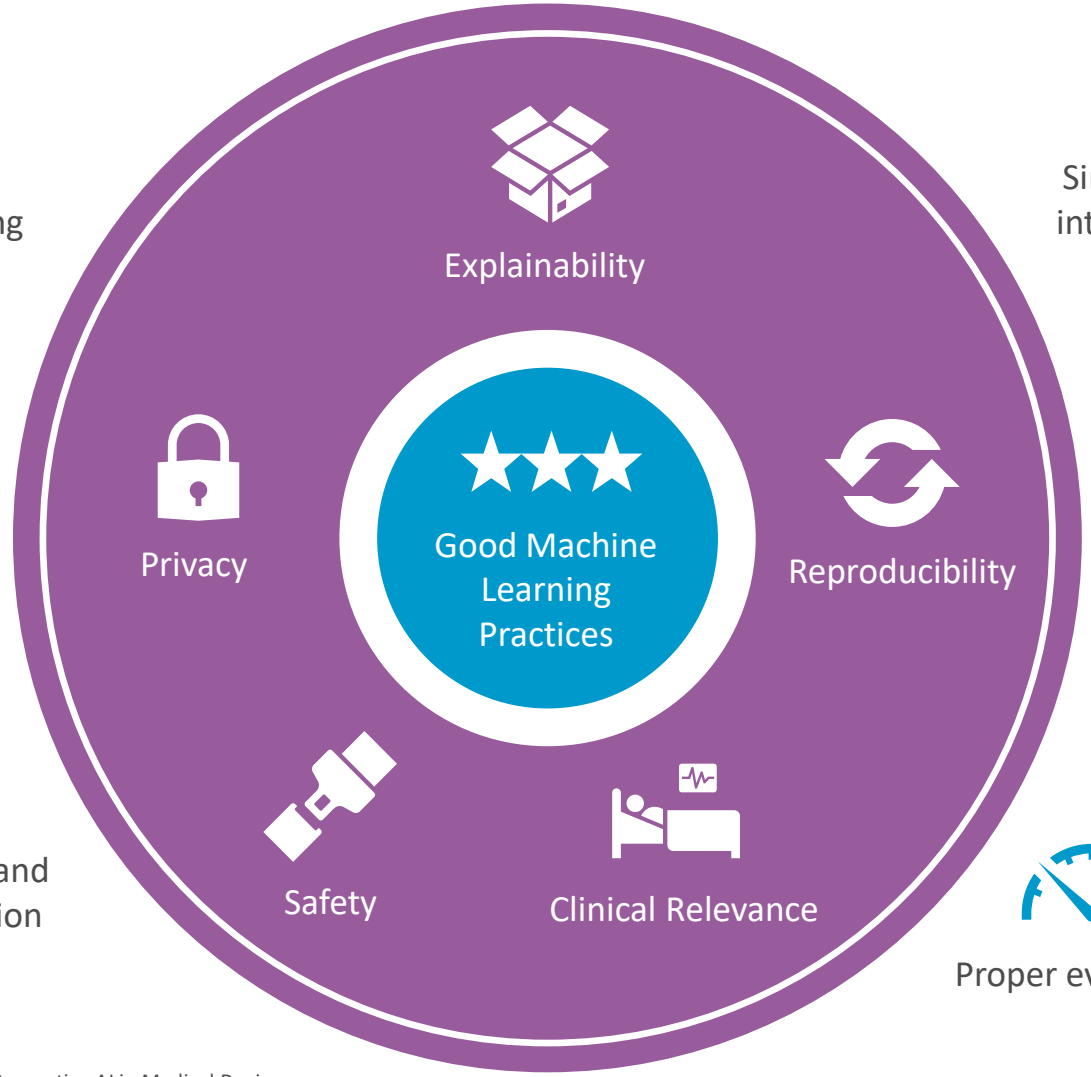
The Promise of AI for Health: Reimagining Medicine

“ Restore the care in medical care”

Eric Topol

AI For Health

The Challenges of AI for Health and How We Tackle Them



Security and Federated Learning

AI & Regulatory Experts

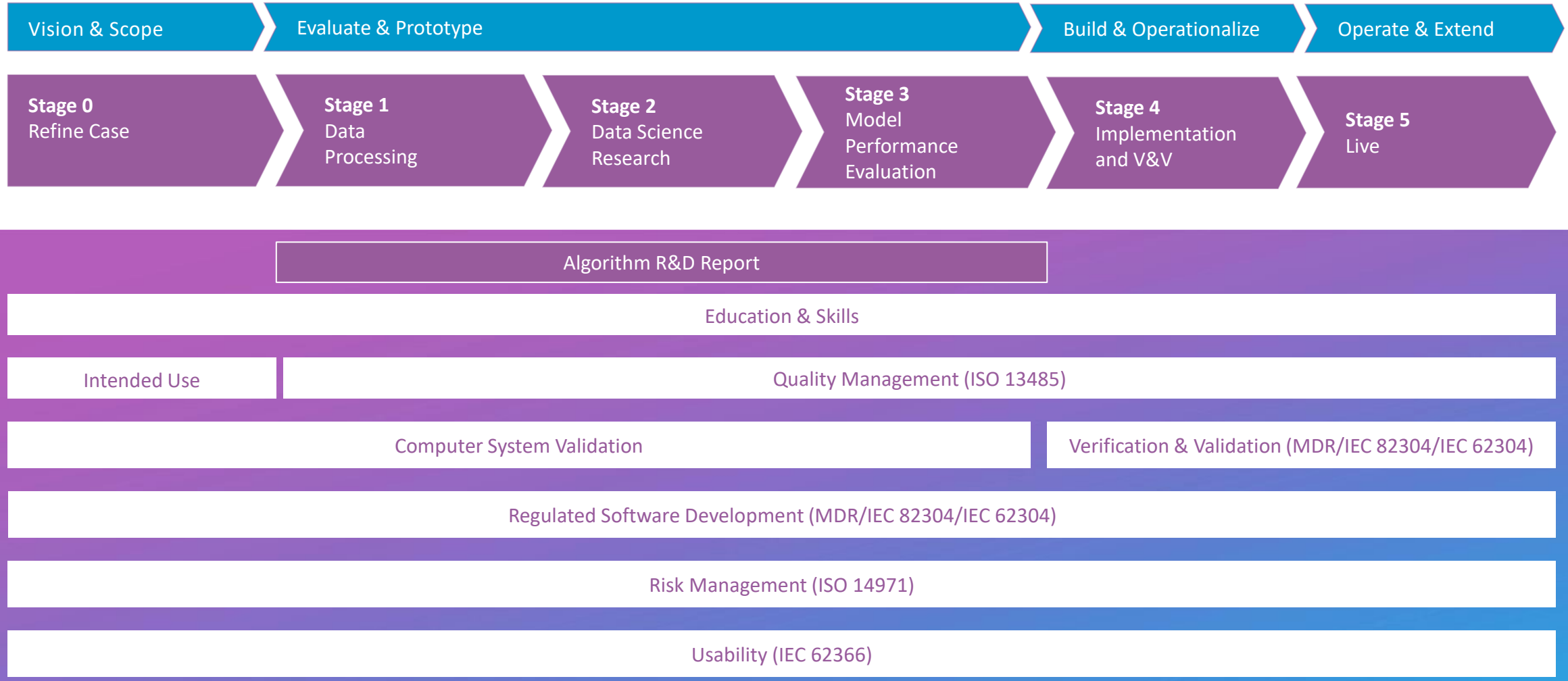
Comprehensively test and document every decision (data, code, risks)

Simple, transparent, interpretable models

Reproducible and fully automated machine learning pipelines

Proper evaluation

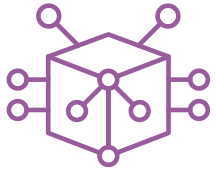
Zühlke Medical AI Process



The Data Science Part

Preprocessing → Training → Evaluation → R&D Report

Validated approach and System



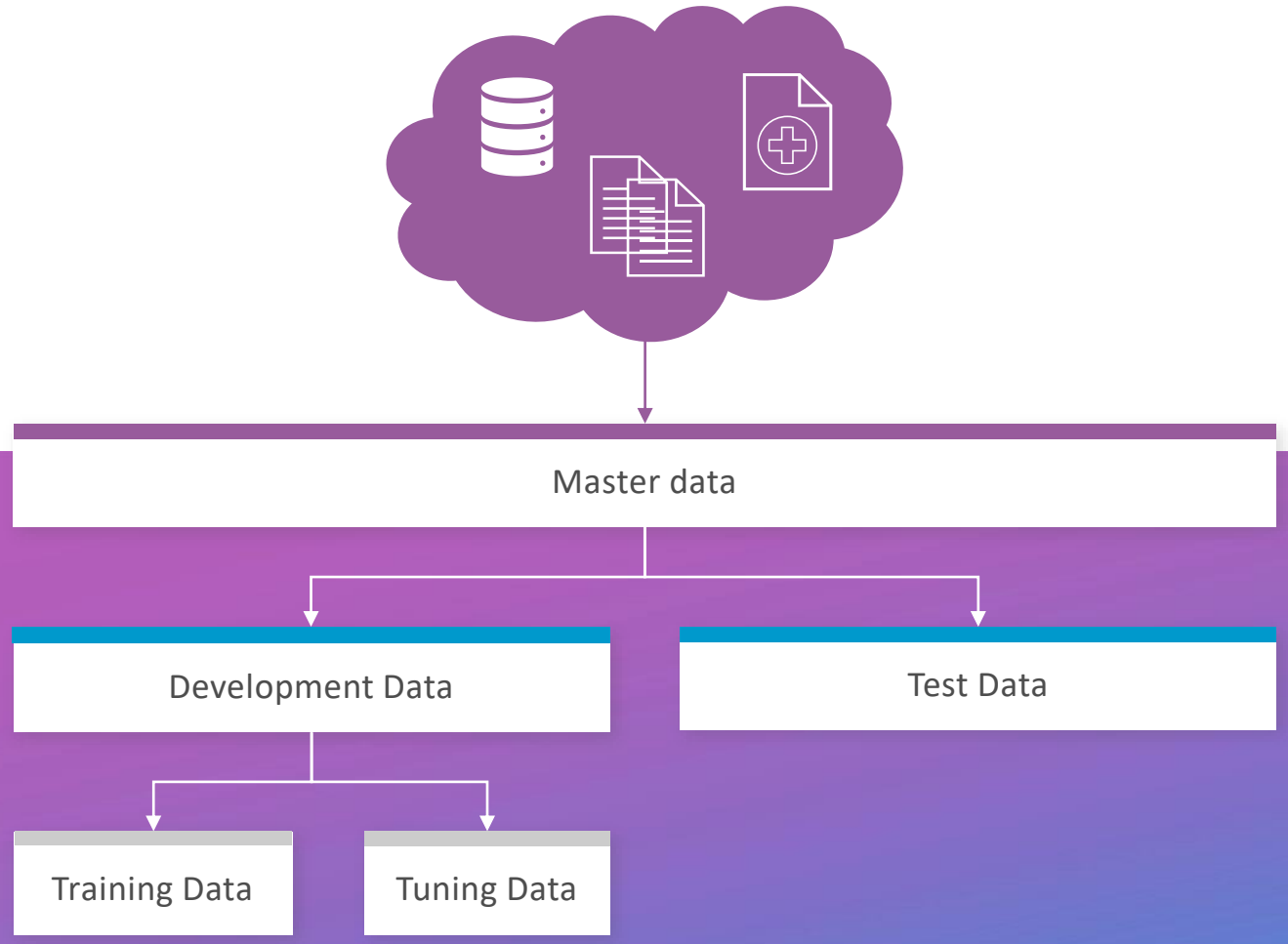
Model

SaMD

+ App (Frontend, Backend)

Preprocessing → Prediction → Monitoring

Data Processing



Does it represent the end users?

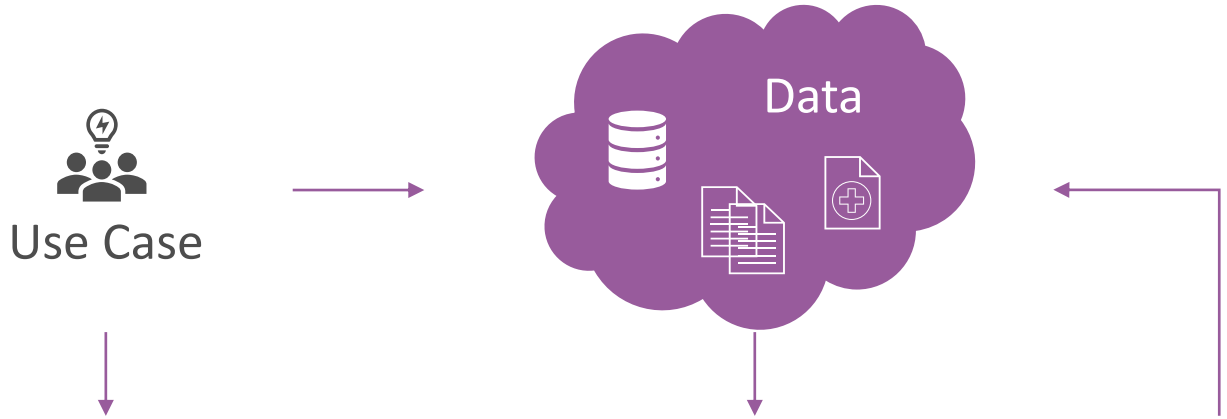
Ground truth

Confounders

Bias

Dataset size

Data Science Research



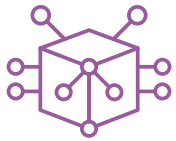
Quality Management (13485)

Computer System Validation

R&D Report

Model Performance Evaluation

Model



Intended Use

Test Data

Split from development data

External data

Robustness and sensitivity analysis

Inspection of mistakes

Baselines

Analysis of explainability

Finalize R&D Report

Clinical study after development

Validation Data

Generative AI

- ChatGPT
- DALL·E 2
- Bard
- stability ai
- Med-PaLM

ChatGPT: Text Generation, Aligned to Human Expectations

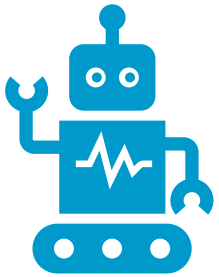
High quantity,
low quality

Train

Low quantity,
high quality

Finetune

ChatGPT



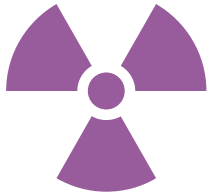
Risks of Large Language Models

False Statements With High Confidence

Biased & Harmful Generations

Legal Uncertainties

Misuse

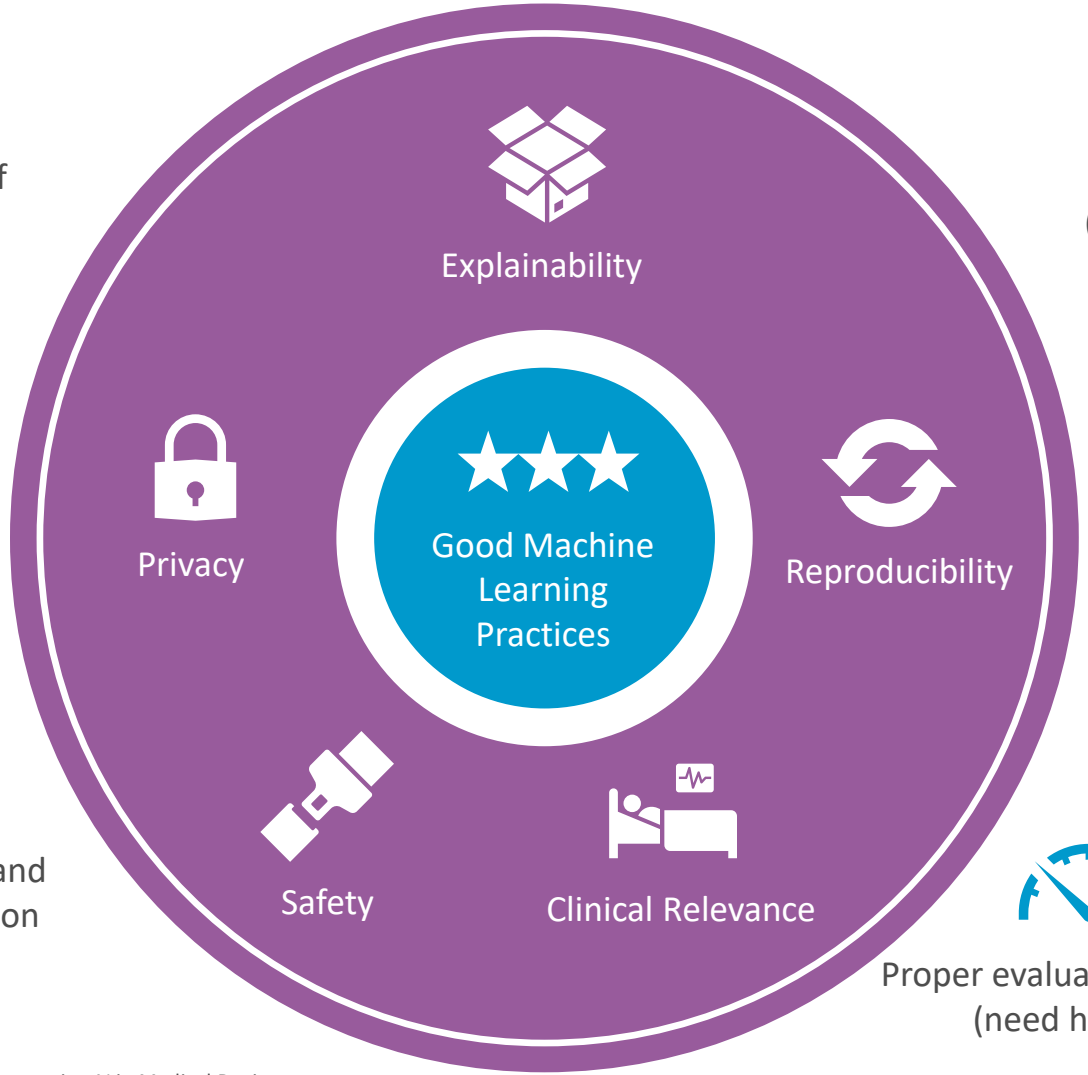


Generative AI in a medical setting – still many open questions

Private hosting of the model

Risk evaluation – select the right use cases

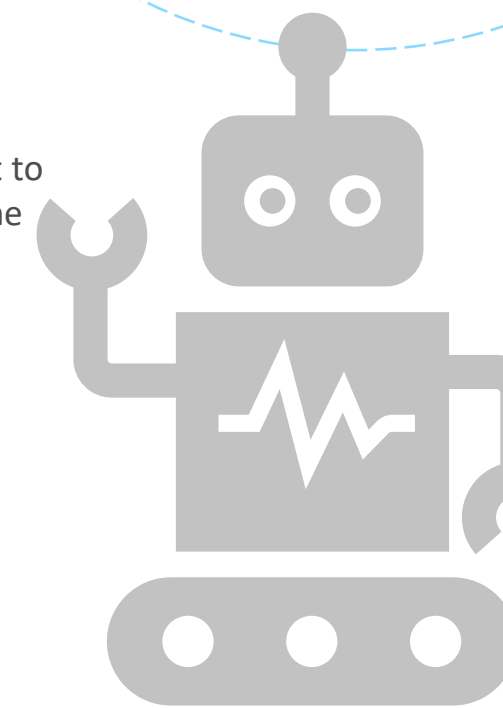
Comprehensively test and document every decision (data, code, risks)



Transparency (talking to an AI , limitations)

Restricting the output to make sure to limit the answers

Proper evaluation is harder (need humans)



Best Practices from Zühlke Medical AI Process

Data processing

- Validated code for data processing and splitting
- Controlled access to master data
- Analysis of correlation, confounders, and groups
- Necessary size of test data estimated (power analysis)
- Data representative of intended use population
- Documented process for obtaining reference standard

Data science research

- Documentation of all experiments and results
- Version Control System for code, models and data
- Re-sampling and cross-validation for evaluation
- Clinically motivated metric for evaluation
- Computer System Validation
- Algorithm Research & Development Report
- Favor simpler, more robust models with better explainability, fewer and simple features

Model performance evaluation

- Point of no return: Validation data cannot be used repeatedly
- Validated code for evaluation and metric computation
- Algorithm Research & Development Report
- Evaluate metric, data and performance requirements against intended use
- Comparison to simple baseline, human performance and state-of-the-art
- Analysis of explainability
- Performance on out-of-distribution data

Contact data

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Zühlke Academy: Medical AI Course
https://www.zuehlke.com/en/medical-ai-how-to-successfully-build-compliant-solutions

Zühlke Whitepaper on Medical AI
https://www.zuehlke.com/en/whitepaper-pharma

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