



zühlke
empowering ideas

The logo consists of a solid purple square containing the text 'zühlke' in a white, lowercase, sans-serif font. Below it, the tagline 'empowering ideas' is written in a smaller, white, lowercase, sans-serif font. The logo is centered on a white background. Two large, dashed circles are visible: a light blue one on the left and a light grey one on the right, both partially cut off by the edges of the frame.

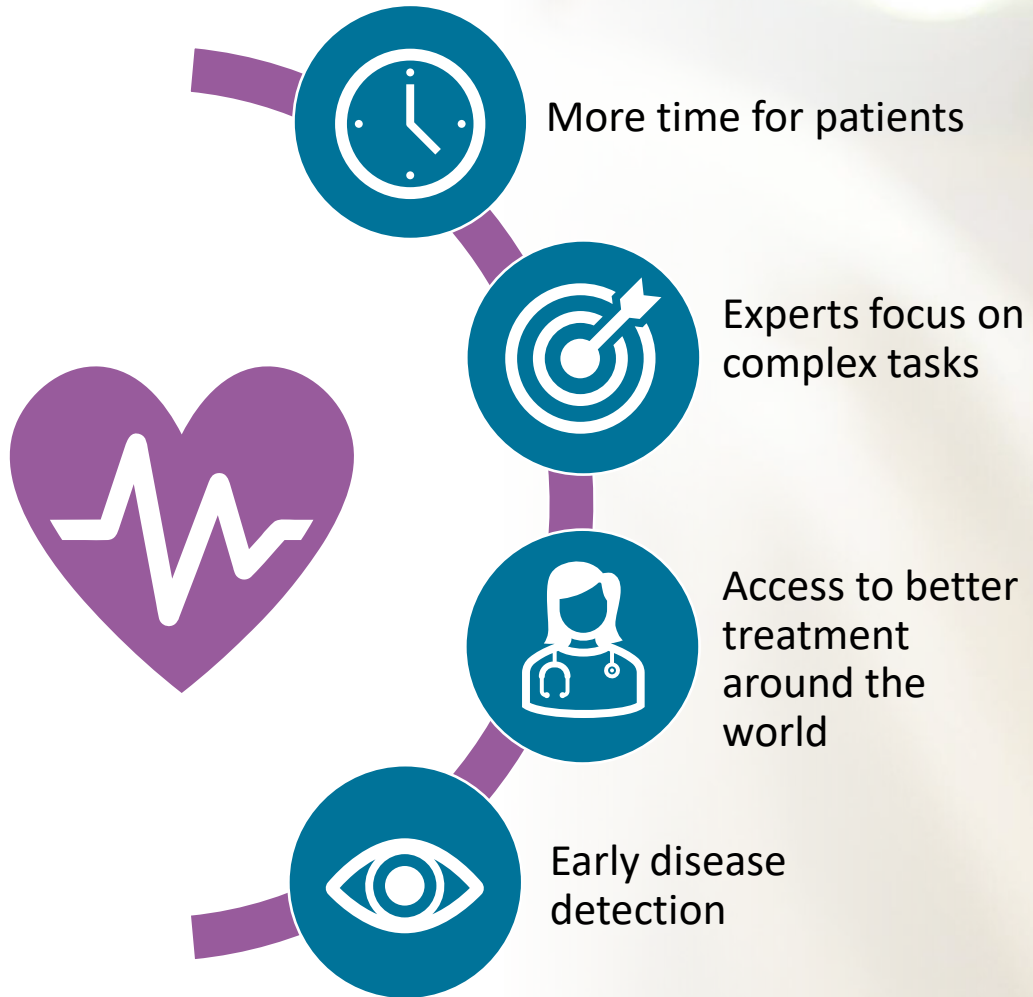


Implementation of Machine Learning in Medical Devices

Swiss MedTech day 2022

Dr. Gabriel Krummenacher & Dr. Lisa Falco

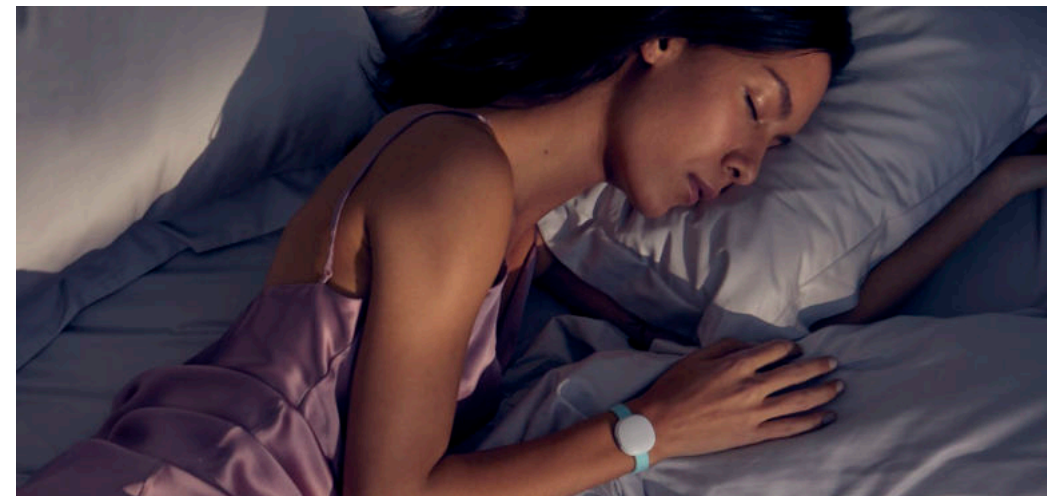
The Promise of AI for Health: Reimagining Medicine



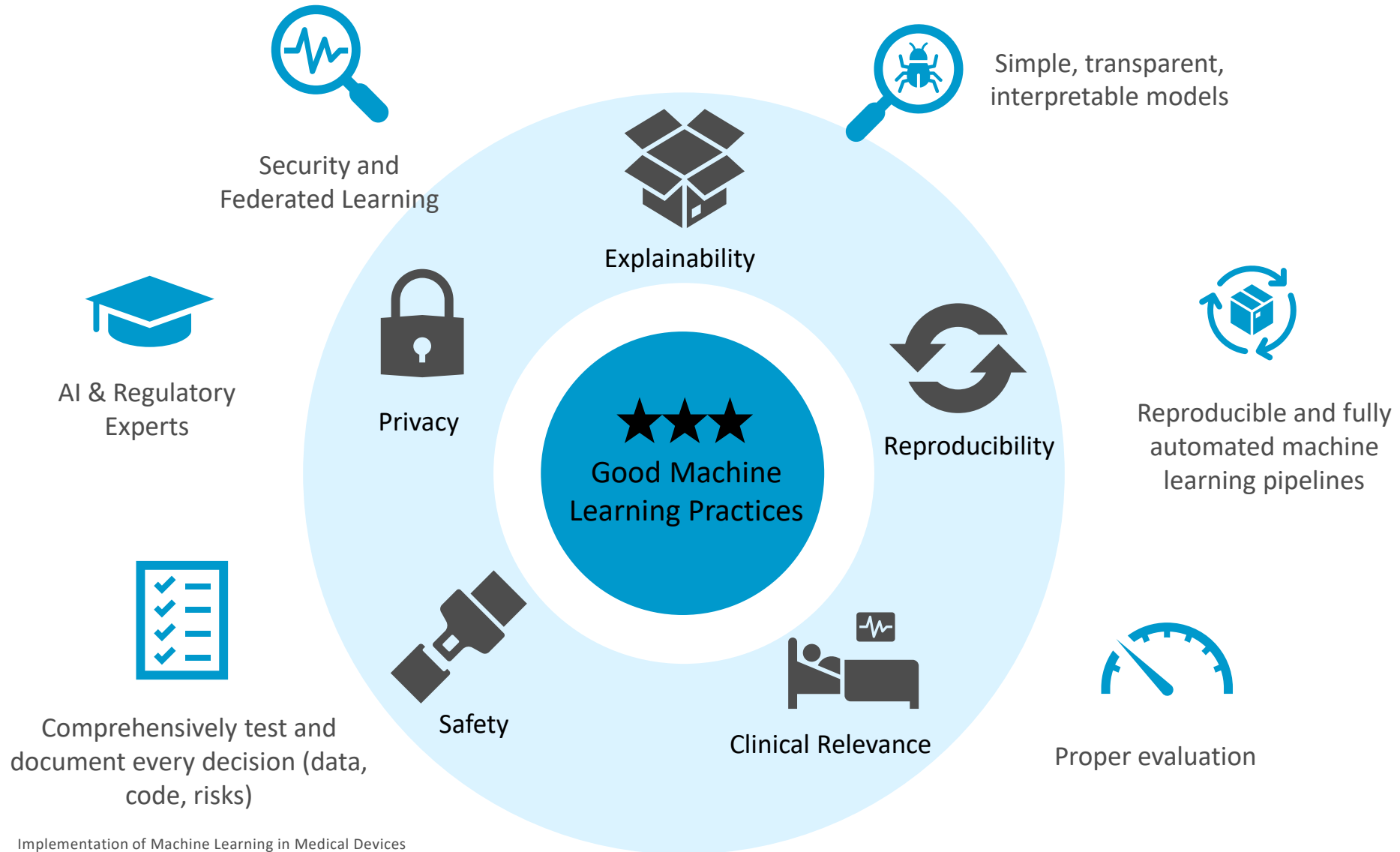
“Restore the care in medical care”

Eric Topol

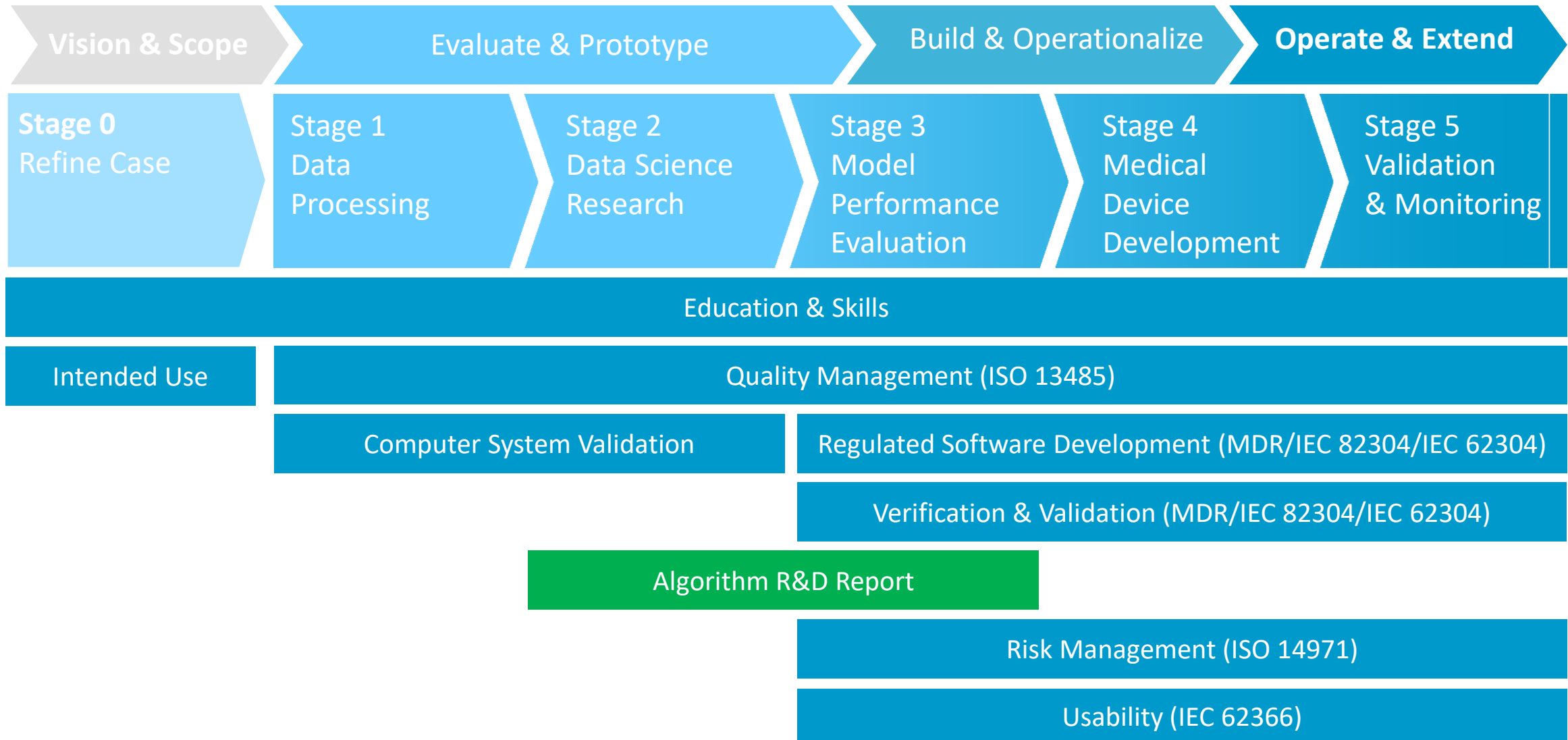
AI For Health



The Challenges of AI for Health and How We Tackle Them

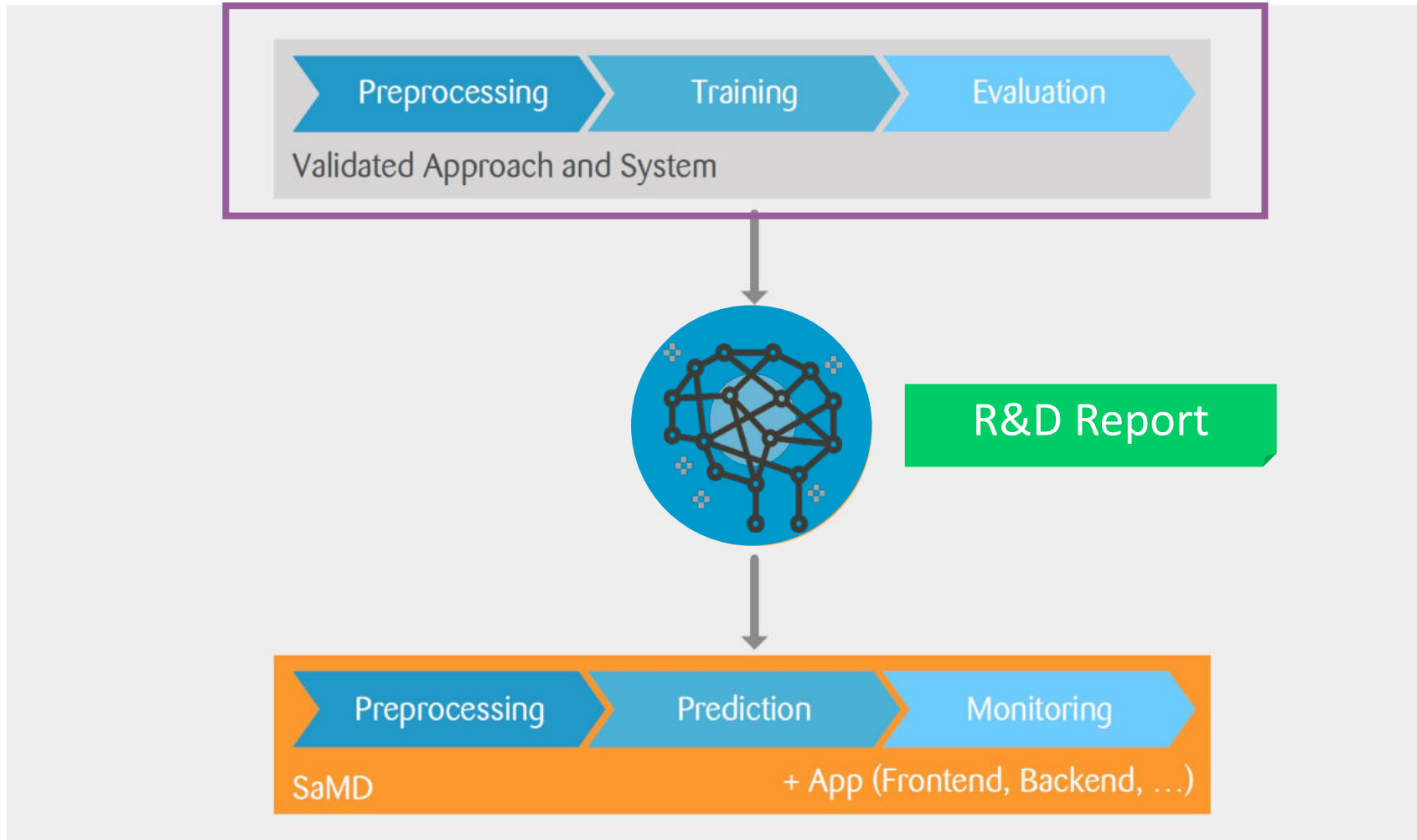


Zühlke Medical AI Process



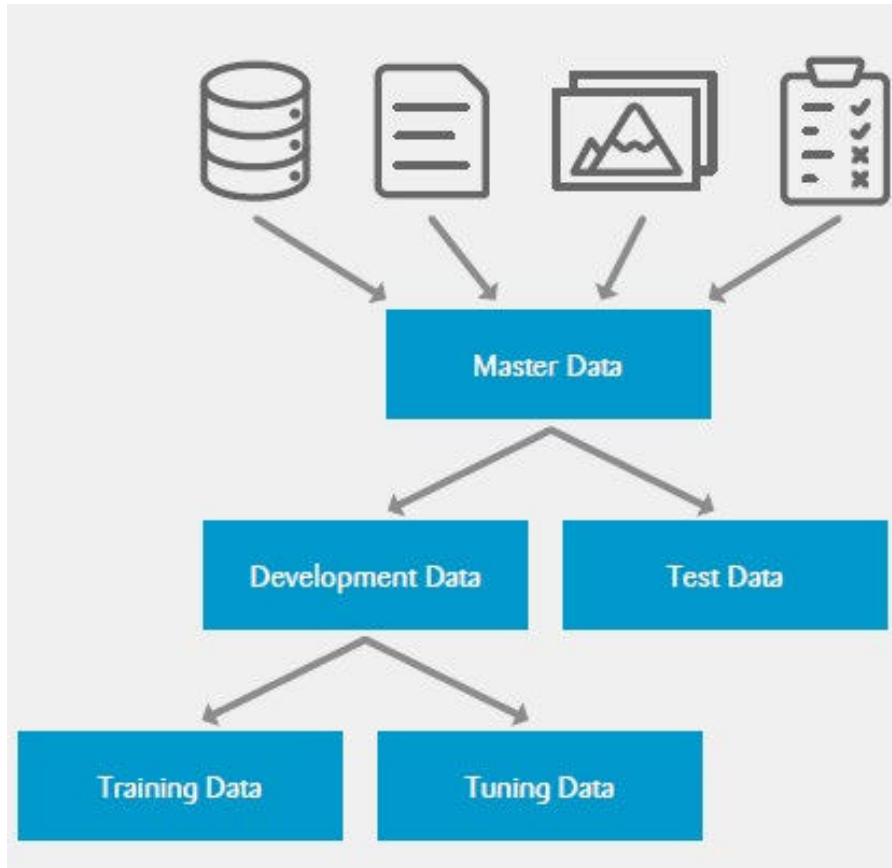
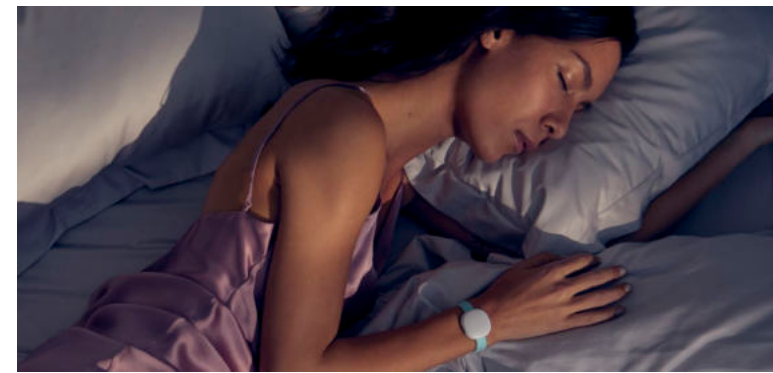
The Data Science Part

Public

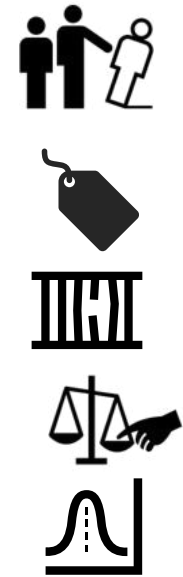


Data Processing

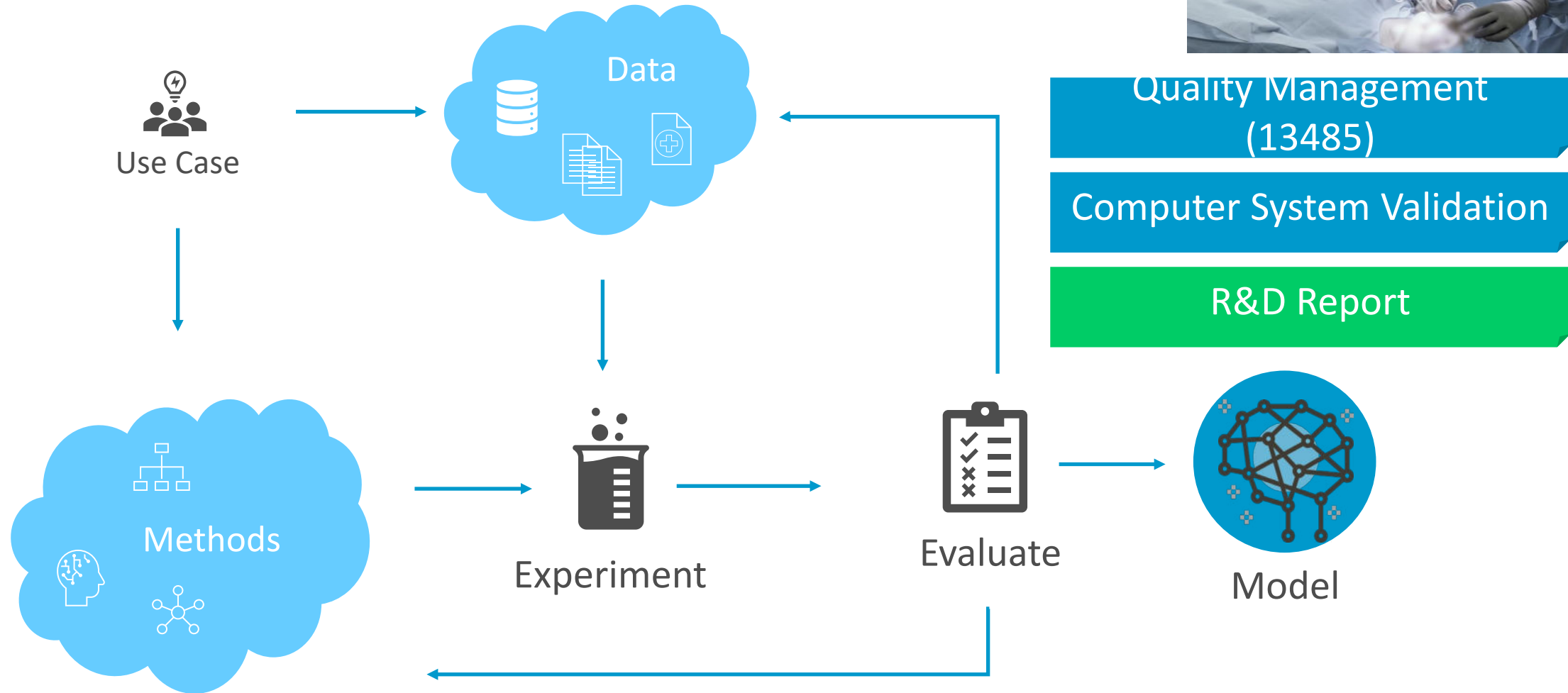
You need to understand & document everything about your data



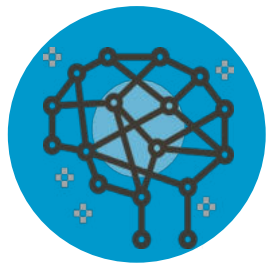
- Does it represent the end users?
- Ground truth
- Confounders
- Bias
- Dataset size



Data Science Research



Model Performance Evaluation



Model

Intended Use



Test Data

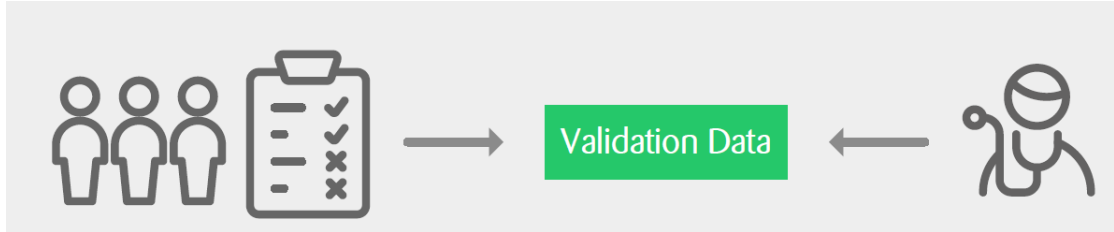
- Split from development data
- External data

- Robustness and sensitivity analysis
- Inspection of mistakes
- Baselines
- Analysis of explainability



Finalize R&D Report

Clinical study after development



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 can not 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








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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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