A Computer Scientist‘s Guide

Artificial Intelligence in Healthcare

Dr. Christina Biermann

Disclosure Statement

Dr. Christina Biermann

I hereby disclose that I am currently employed by **Bayer AG** and have entered a contract with **Siemens Healthineers**, which is set to begin on November 1st. I confirm that I have no other affiliations or relationships with any other organizations or entities.

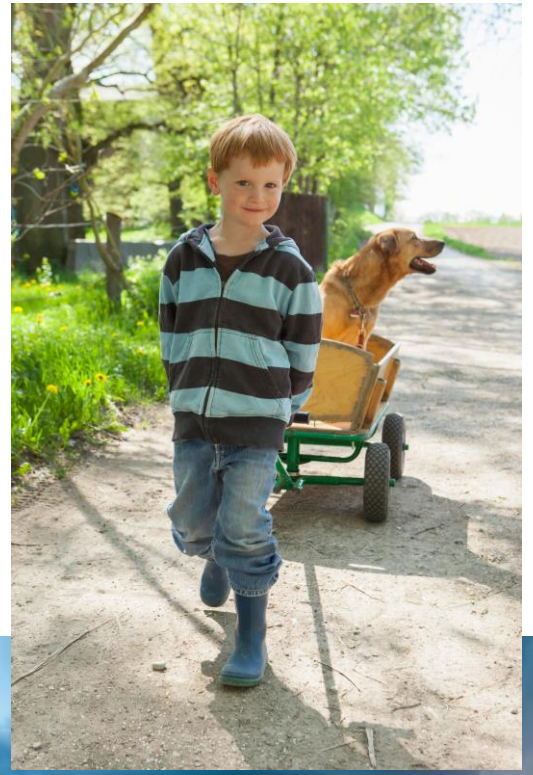
Over 20 Years Passionate Experience in AI and Healthcare

Dedicated to Enhance Patient Outcomes Through Innovative Technologies

Expectation Setting

AI in Healthcare: A Computer Scientist‘s Guide

- Basic terminology and Healthcare Challenges
- Opportunities for AI to revolutionize diagnostics and patient outcomes
- Challenges in general and in particular for computer scientists
  - Data, Bias & Regulatory compliance
- What needs to be considered to overcome challenges



- Severe diseases
- Interaction with seat neighbors and me

AI in Healthcare

Your Interactions Until Now?

Your feedback

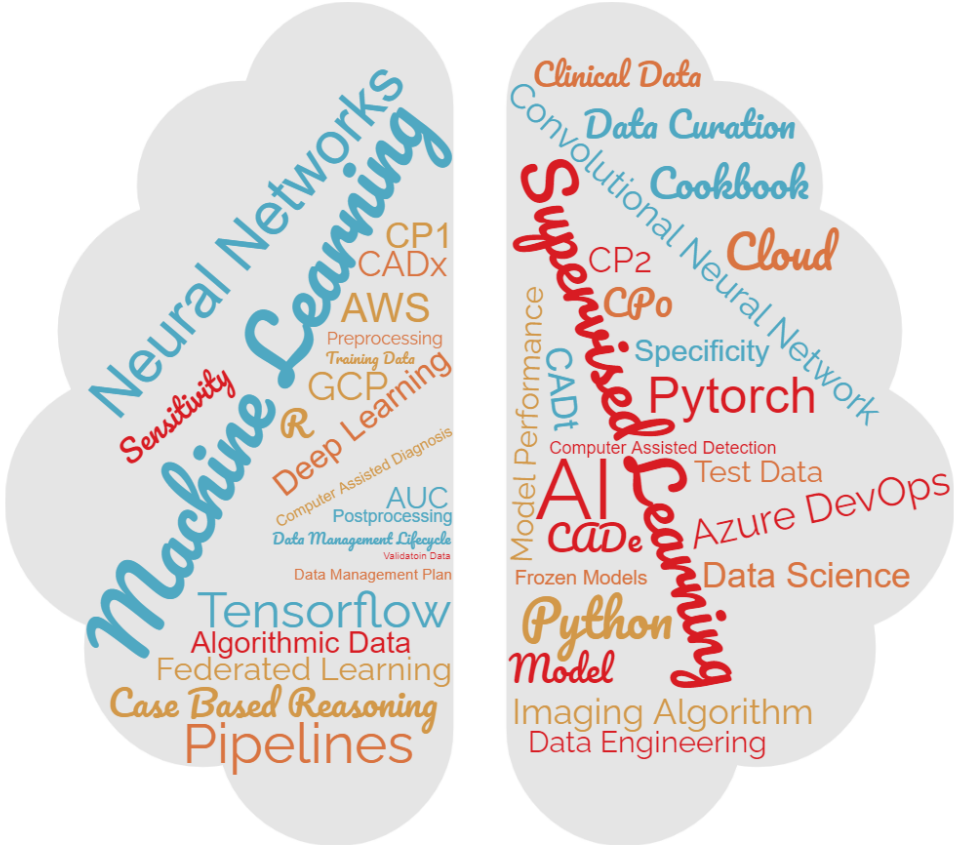
- Who has implemented AI algorithm already?
- Who has used AI in a healthcare context?
- Who has implemented AI algorithm in healthcare context?

Source: Right image created with designer.Microsoft.com/image-creator

How are the terms related to each other?

Clarification of Terminology

3min time to discuss the right order with your neighbor



// Artificial Intelligence
// Deep Learning
// Generative AI
// Machine Learning
// Neural Network

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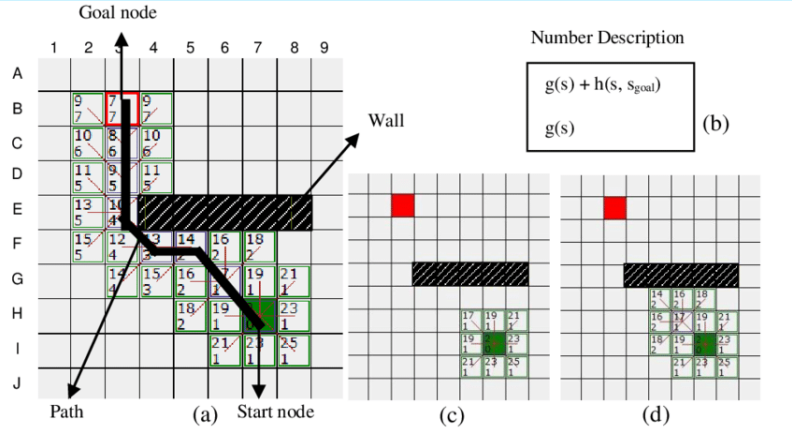
Artificial Intelligence

Computer Science Example

A* algorithm



Source: Illustration of A* algorithm path planning | Download Scientific Diagram (researchgate.net)

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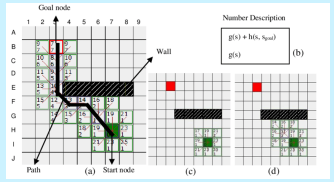
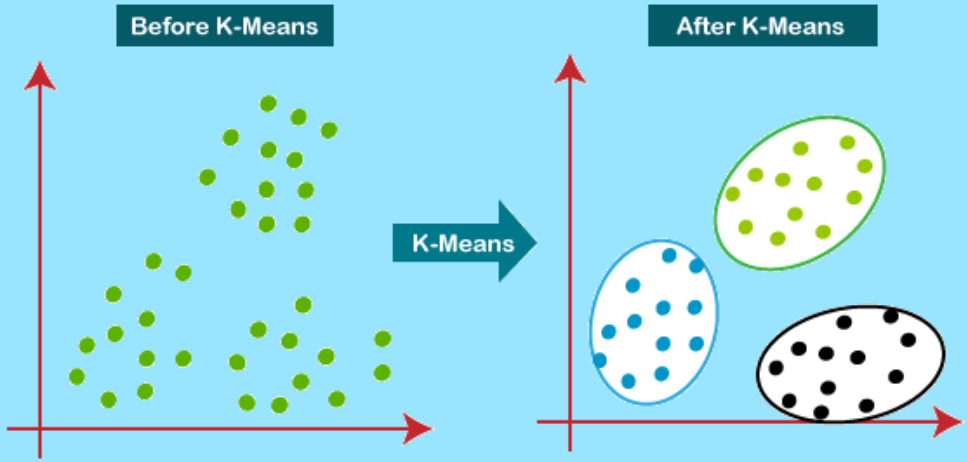
Artificial Intelligence



Machine Learning

Computer Science Example



Source: K-Means Clustering in Python and How Does it Work? (analyticsvidhya.com)

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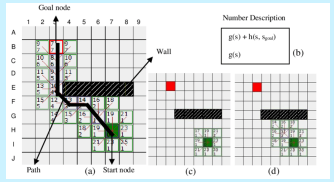
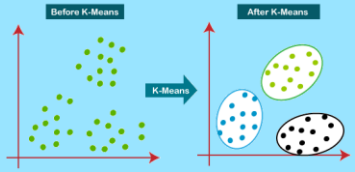
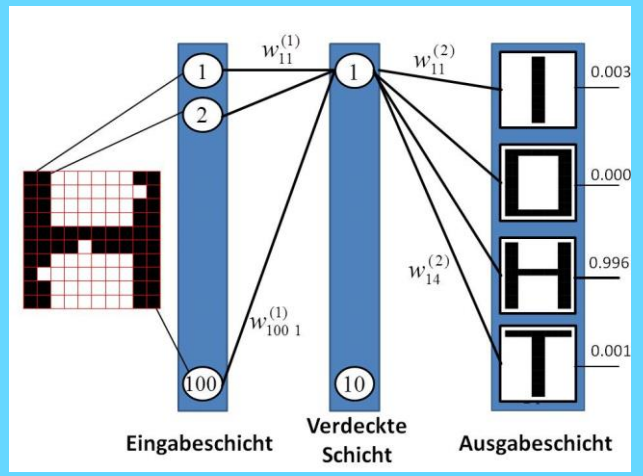


Machine Learning



Neural Network

Computer Science Example



Source: Neuronale Netze – Sebastian Dörn (sebastiandoern.de)

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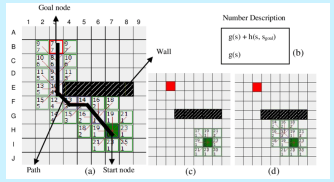

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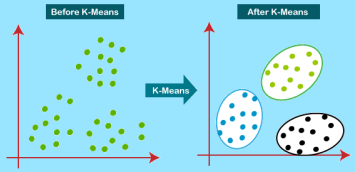

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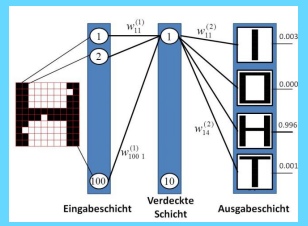
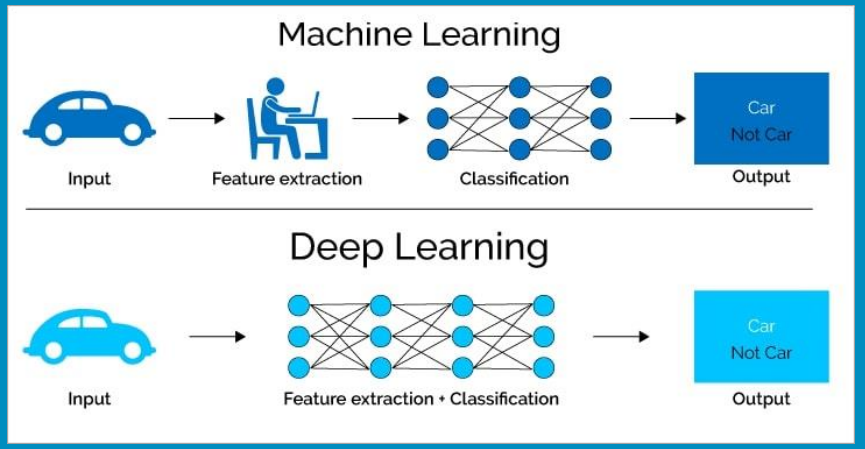


Deep Learning



Source: Deep Learning vs. Machine Learning – What's The Difference? (levity.ai)

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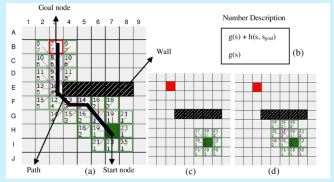

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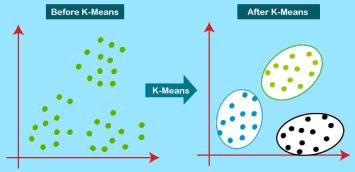

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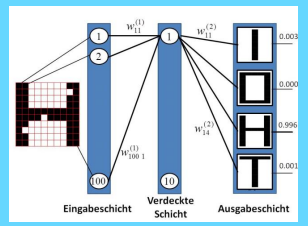
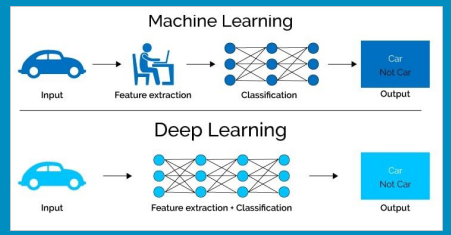


Deep Learning



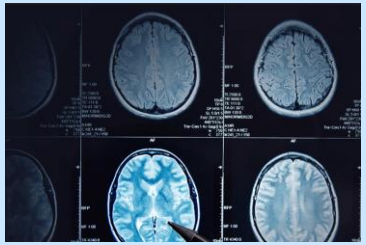
Generative AI

ChatGPT

DALL·E

Which kinds of Software do exist in Healthcare?

Clarification of Terminology

Terms	Definitions	Examples
Software in a Medical Device (SiMD)	SiMD is defined as software that is a part of a medical device or controls it (embedded software)	
Software as a Medical Device (SaMD)	Software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device	
Machine Learning Enabled Medical Device (MLMD)	A medical device that uses machine learning, in part or in whole, to achieve its intended medical purpose.	

Current State of Healthcare vs Vision for Future utilizing AI

Paper and People Power vs Providing Available Data to the Experts When Needed

Scenario 2024

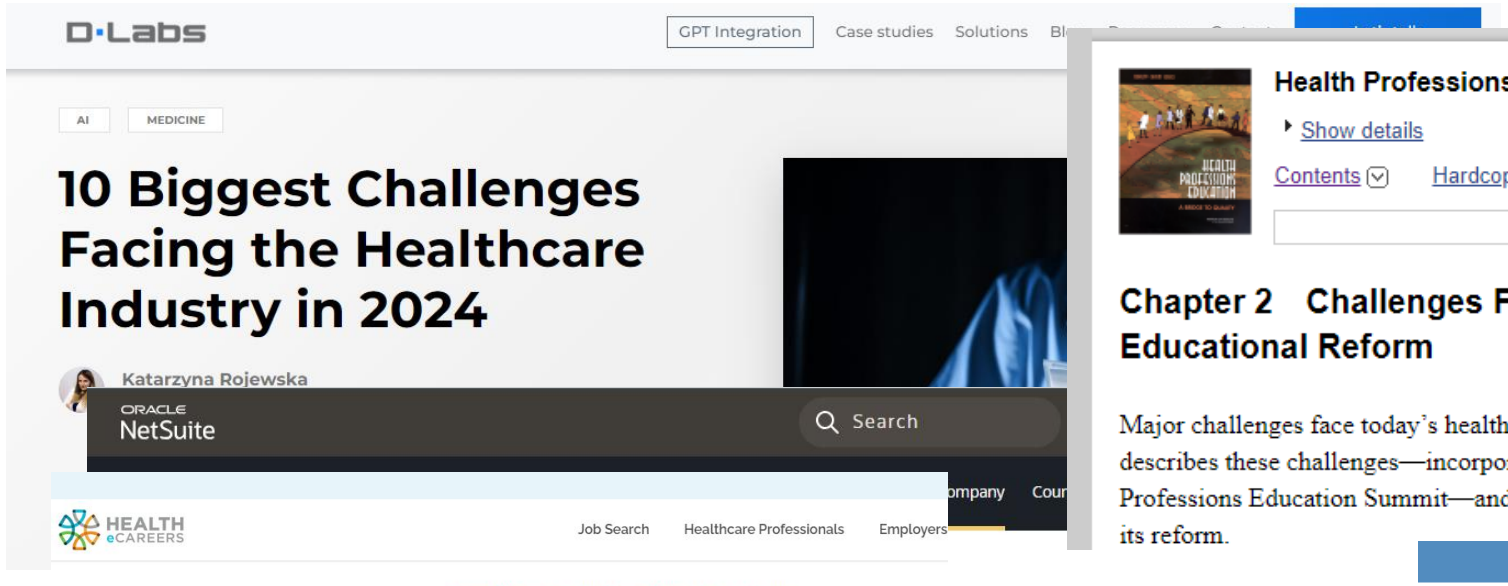
Current State of Healthcare vs Vision for Future utilizing AI

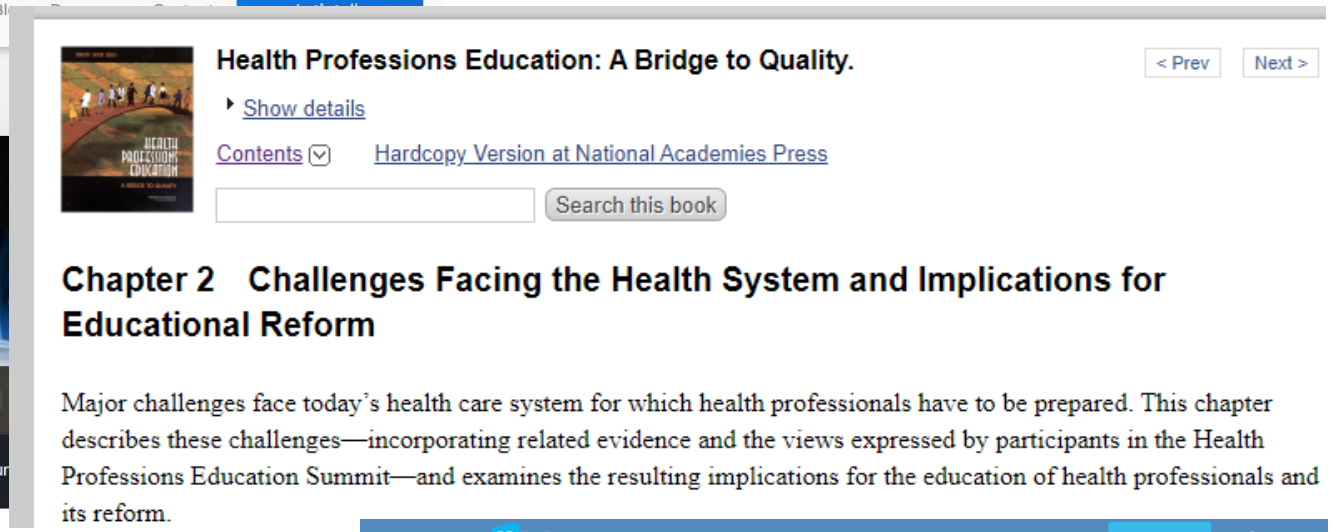
Paper and People Power vs Providing Available Data to the Experts When Needed

Scenario 2034

Challenges in Healthcare are Driven by Demographic Change

Different Perspectives on the Healthcare – Patients, HC Provider, Pharma, Device Industry, …





5 Common Challenges in Healthcare

Different Players with Different Perspectives Sharing Same Concerns About Healthcare,

“If the only tool you have is a hammer, you tend to see every problem as a nail.”

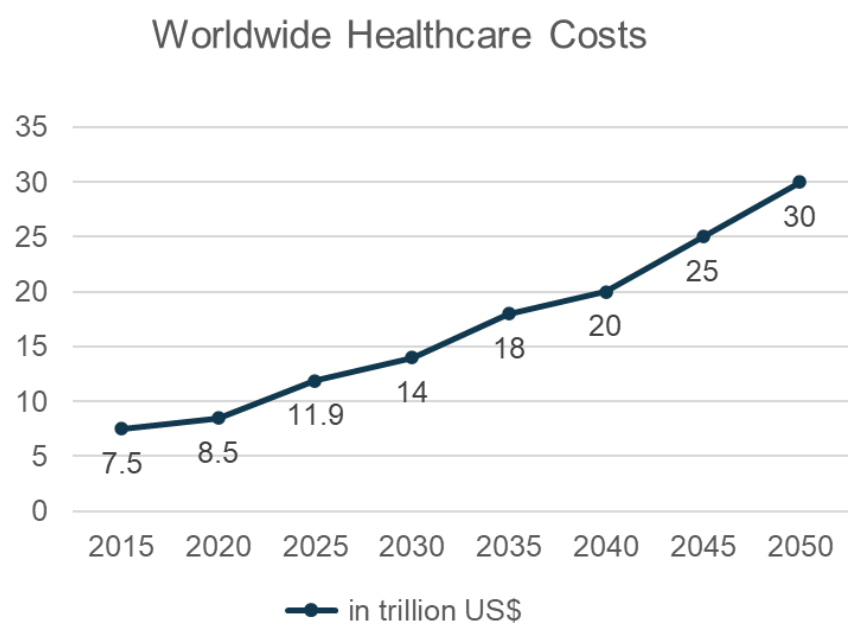
Abraham Maslow, 1966

How Can Digitalization and AI Help to Lower Continuous Increase of Cost of Care?

Different Drivers for Costs Increase Foster Different Solutions

Aging Population

Chronic Disease



Rising Income Levels

Technology Advancements

Source: Data Points derived with support of MyGenAssist – Bayer ChatGPT version

Electronic Health Records are an Opportunity for Healthcare Providers to Lower Costs

How Can Digitalization and AI Help to Lower Continuous Increase of Cost of Care?

Electronic Health Record (EHR) can lower costs for hospitals up to 12%* and for outpatient care by ~3%**

*) Highfill T (2019), Do hospitals with electronic health records have lower costs? A systematic review and meta-analysis.
**) Adler-Milstein J (2013), Effect of Electronic Health Records on Health Care Costs: Longitudinal Comparative Evidence From Community Practices.

AI Can Improve Operational Efficiency

How Can Digitalization and AI Help to Lower Continuous Increase of Cost of Care?

Modality Selection & Scheduling

Patient set-up & injection

Image Acquisition

Worklist Prioritization

Reading

Diagnosis & Reporting

Administration & Analytics

Results Communication

Treatment Planning & Execution

Planning | Scan room | Reading room | Administration | Treatment room

From fragmented digital ecosystems > to fully integrated radiology workflows

Digitalization and AI Help to Lower Time to Market and Decrease Costs for Industry Players

Various Opportunities for Pharma and Device Industry to Lower Costs

Workforce Shortage is a World-Wide Challenge

Similar Problems with Different Solutions for Different Areas of the World

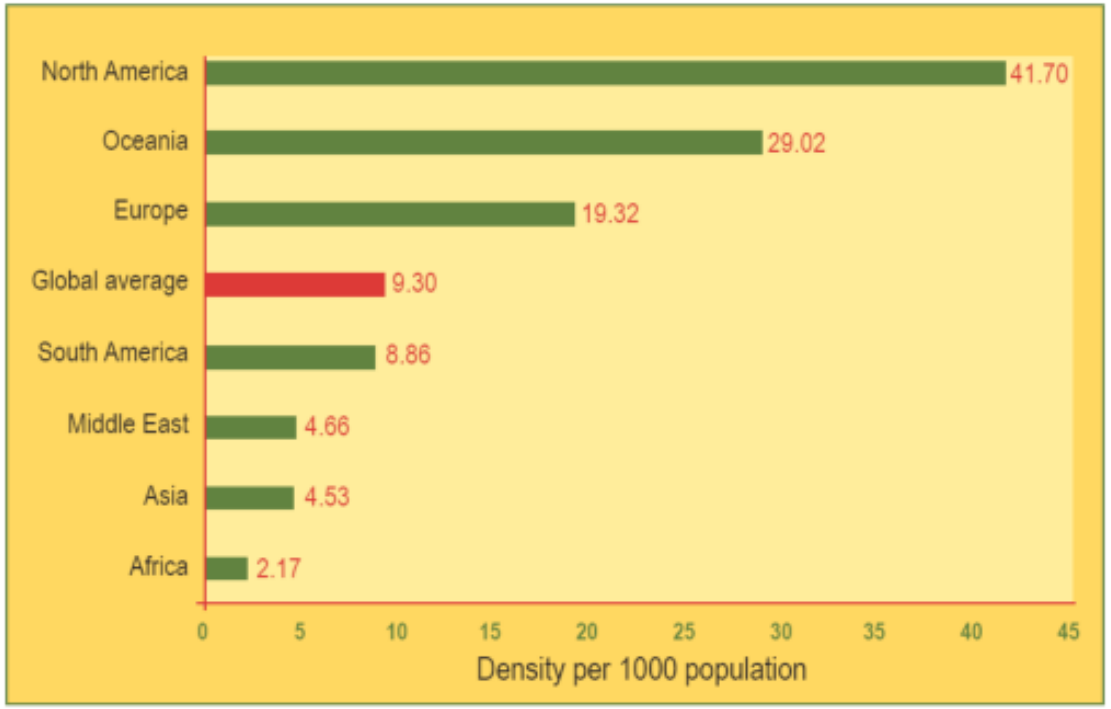


Table: Inequities in distribution of health workers worldwide (WHO 2006)

Different Solutions for Different Areas of the World?

Workforce Shortage is a World-Wide Challenge

Developed Countries

- Support of Documentation
- AI in Radiology
- Patient Education
- Identification of Findings

Developing Countries

- Mobile Apps for Symptom Assessment

ada

- Telemedicine
- Remote Access
- Diagnosis of Specific Disease

Workforce Shortage Mitigation Solutions are also a Means to Improve Access to Care

Developing & Developed Countries

Mobile Apps for Symptom Assessment

ada

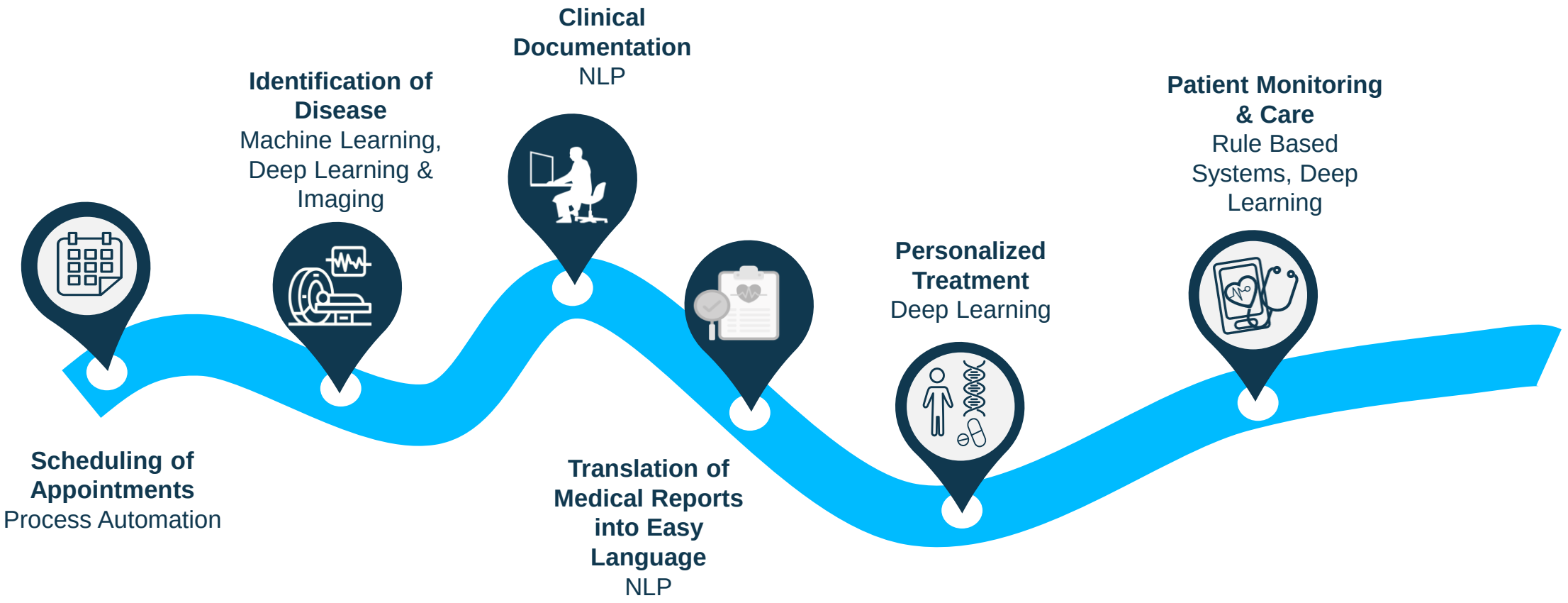
Telemedicine

Remote Access

Diagnosis of Specific Disease

AI Can Increase Quality of Care During the Whole Patient Journey

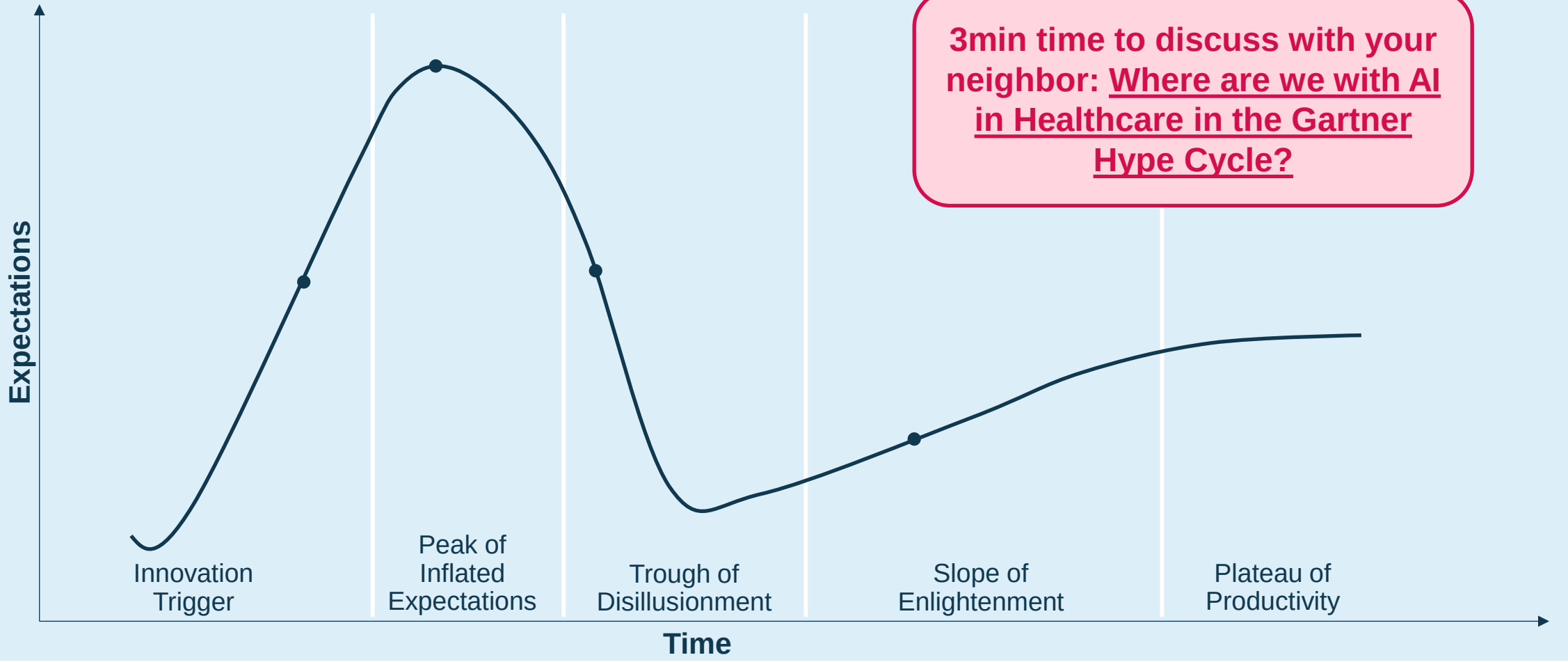
Supporting Patients from Appointment Scheduling to Translation of Medical Reports and Care



AI is Part of the Fifth Challenge „Digital Transformation and Technology Adaption“

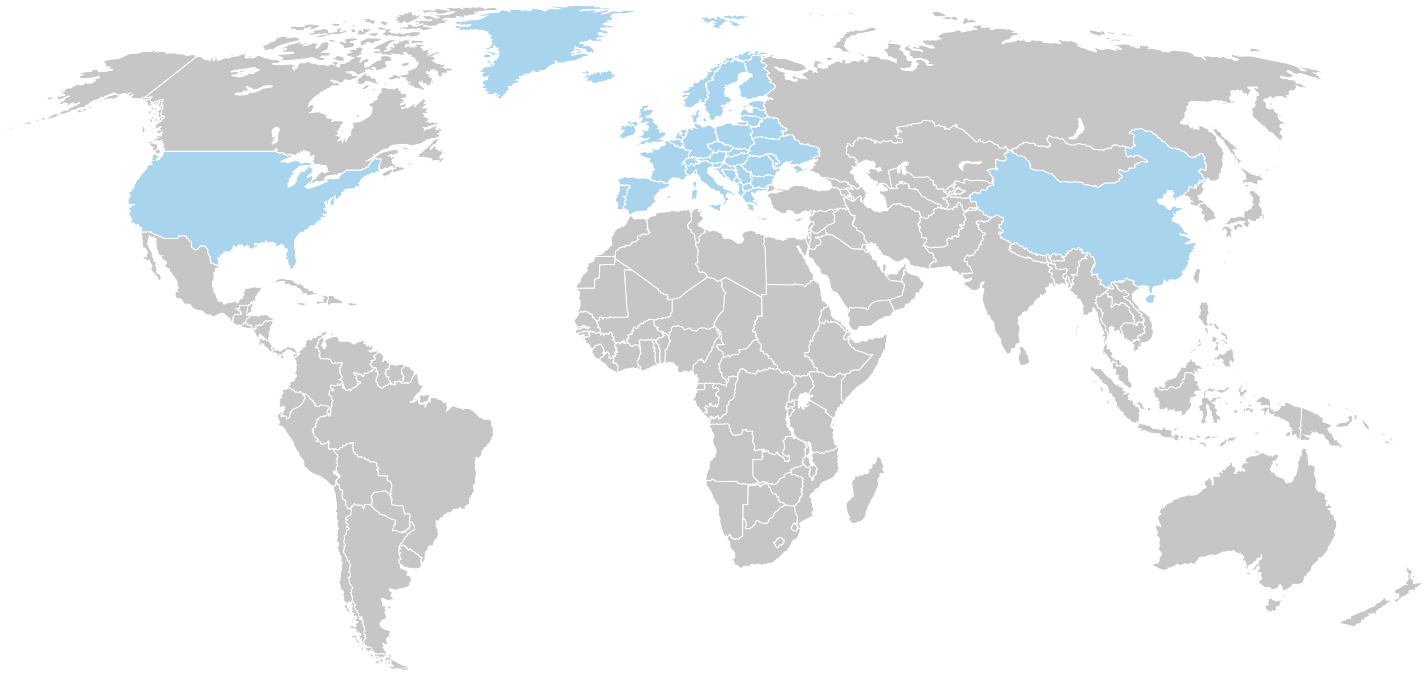
Gartner Hype Cycle – Where are we at the moment with AI in Healthcare?

3min time to discuss with your neighbor: Where are we with AI in Healthcare in the Gartner Hype Cycle?



AI in Healthcare Faces Additional Implementation Challenges

Huge Market and Long List of Opportunities, but Slow Adaptation of AI in Healthcare



Estimated Global Artificial Intelligence in Healthcare Market

- **2024: >20bn US$** [20.04 - 28.61bn US$]*
- **CAGR: >36.8%** [36.83 – 48.5%]*

- **Data Collection Challenge**
  - Fragmented legal landsscape (e.g. HIPAA, GDPR, and additional local restrictions)
  - Sufficient number of representative patients
  - Lack of informed consent and locally varying conceptions of ethics committees
  - Data availabiltiy and costs
- **Regulatory Landscape**
  - US – FDA and *Executive Order*
  - EU – MDR and *EU AI Act*
  - China – NMPA and *AI Measures*

*) Research results from 7 provider: copperdigital.com, precedenceresearch.com, researchandmarkets.com, gminsights.com, globenewswire.com, grandviewresearch.com, towardshealthcare.com – more details in Alt Text

Regulatory Landscape and Speed of Changes

Different Regulatory Requirements in Different Countries with Common Goals

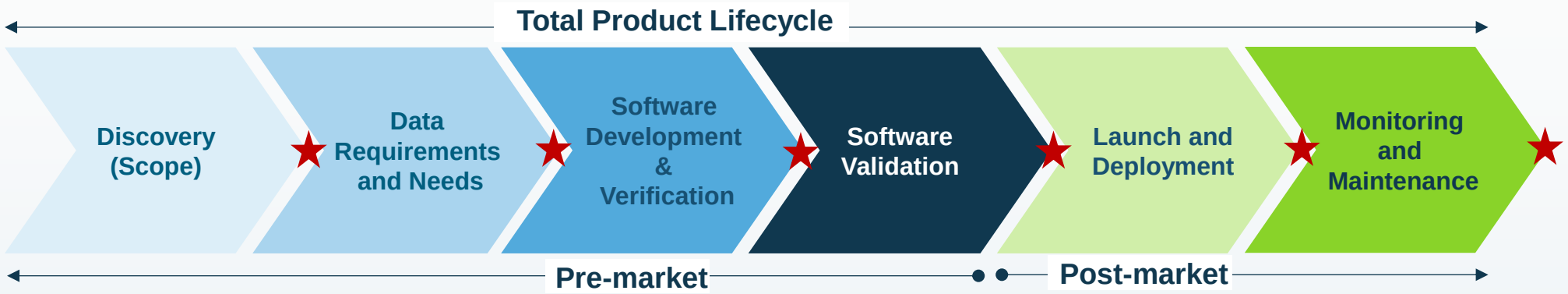
- Protecting Patient **Data Privacy** and **Security**
- Ensuring **Safety** and **Efficacy** of AI systems
- Addressing potential **Bias** and **Fairness**
- Mandate **Transparency** and **Explainability**
- Requiring **Clinical Validation** to provide demonstration of **clinical benefits** and **improved patient outcomes**
- **Post-Market Surveillance** for ongoing monitoring

Development Lifecycle to Fulfill Customer Needs and Regulatory Requirements

A Stage Gate Approach of a Cross-Functional Team

80% AI & ML projects are delayed

ref



Discovery Phase is Setting the Stage for a Successful AI Product Development

Development Lifecycle to Fulfill Customer Needs and Regulatory Requirements

Cross-functional discovery team is assessing desirability, feasibility and viability guided by key question

Desirability – What do we want to improve?

Feasibility – Can we do it?

Viability – Is it commercially sustainable?

Data Requirements and Needs Phase Contains First Experiments and Most Important Design Decisions

Development Lifecycle to Fulfill Customer Needs and Regulatory Requirements

>80% AI project time is spent on data preparation and engineering

ref

96% Companies run into data quality & labelling problems ref

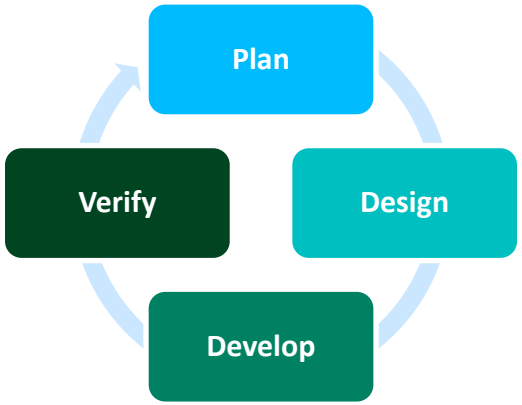
Elements of concept need to be defined

- **Clinical Task/User Workflow** is defined
- **Requirements** are described
- **Data** is defined and collected
- **Model architecture** is determined, and **first Model** is trained
- **Clinical, technical, business KPI‘s** are defined

Customer Satisfaction and Quality is Ensured in the Implementation Phase *Software Development & Verification*

Development Lifecycle to Fulfill Customer Needs and Regulatory Requirements

Software development



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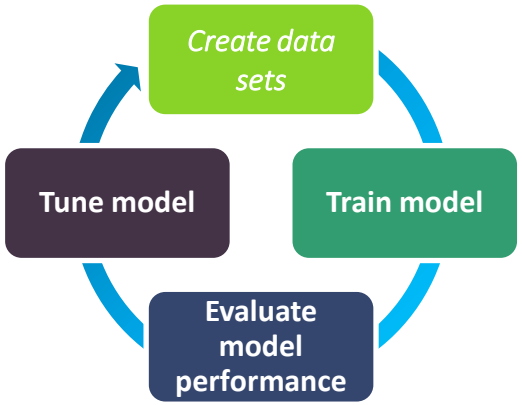
Model training



Formal Verification

Software is tested against all defined requirements in a systematic way using predefined test cases, test data and test techniques

Software Validation Demonstrates Clinical Benefits and Prepares Submission to Health Authorities

Development Lifecycle to Fulfill Customer Needs and Regulatory Requirements

- **Technical validation**
  - // Human Factors Evaluation
  - // Standalone/technical Performance Assessment
  - // Alpha Site
- **Clinical validation (pivotal confirmatory)**
  - // Clinical study to show if the requirements met the user needs.
- **Preparation for health authority submission**
  - // Clinical Evaluation Report
  - // Summative HFE Evaluation Report
  - // Finalize Safety and Security Risk Management (Software Risk Assessment, Use Error Analysis,…)
  - // Finalize Post-Market Surveillance Plan
  - // Finalize Issue & Complaint Management Plan
  - // Finalize Post-Market Clinical Follow-Up Plan
  - // …

Launch and Deployment as well as *Monitor and Maintenance* are Driven by Medical Device Activities

Development Lifecycle to Fulfill Customer Needs and Regulatory Requirements

// **Standard medical device processes** are used to bring AI in Healthcare products to market

// Focus needs to be on **user acceptance of AI** and **seemless integration** into workflow

// **Model and Data Drift** need to be monitored

Many AI Enabled Medical Devices are Supporting Patients Today

3min time to discuss with your neighbor

// How many **AI Enabled Medical Devices** were already cleared by the FDA?

// How many **manufacturer** did it?

FDA has authorized **950 AI/ML-enabled Medical Devices**. Created by **more than 350 companies**.

Source: Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices | FDA
Latest Update: August 7, 2024

AI in Healthcare - Big Opportunities and Big Challenges

Think Big and Start Focused With Engaged Clinical Partner and Regulatory Support

Questions & Answers