

The Use of AI in Market Access in the Pharmaceutical Industry

Enhancing Timing, Predictability and Outcome

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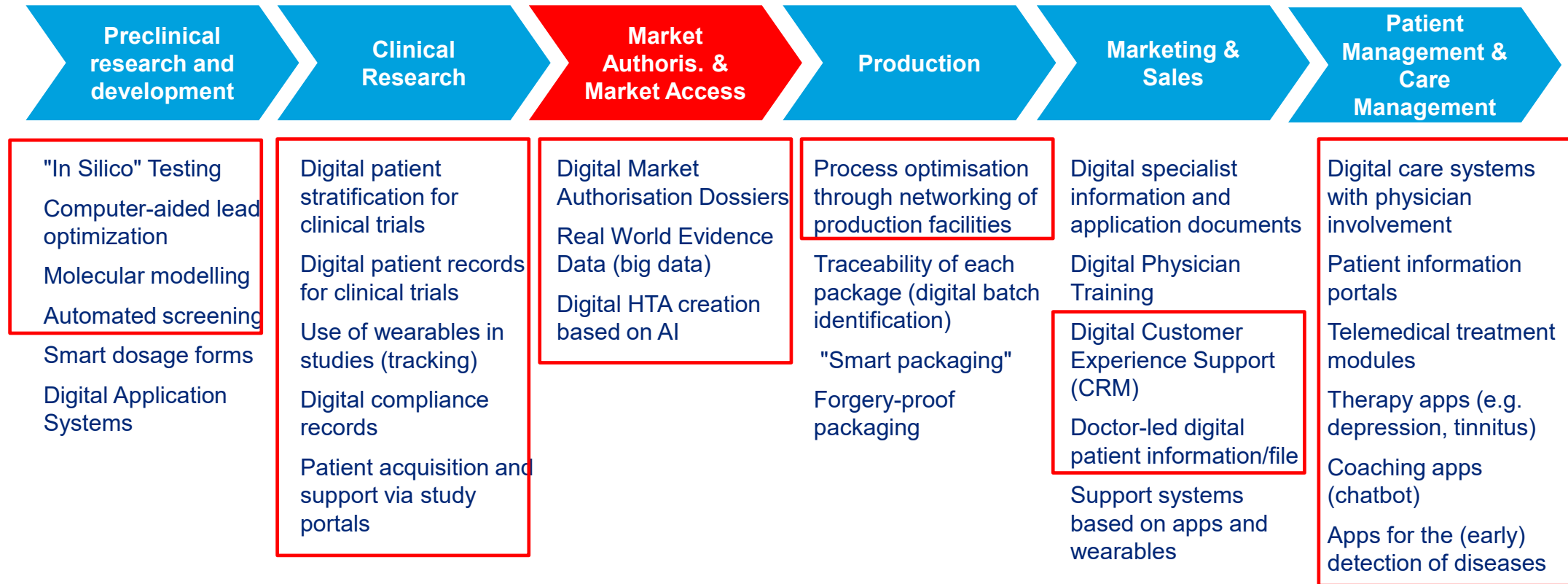
ex Janssen/Johnson & Johnson Innovative Medicine

I. INTRODUCTION

- **Purpose of the Presentation:**
 - Understanding Market Access in Pharma
 - Role of AI in Enhancing Market Access Now and in the Future



DIGITALIZATION IN THE PHARMACEUTICAL SECTOR IN ALL PARTS OF THE VALUE CHAIN



Powered/supported by AI

II. OVERVIEW OF MARKET ACCESS IN THE PHARMACEUTICAL INDUSTRY

- **Definition of Market Access**
 - Ensuring availability of **drugs to patients**
 - Achieving **optimal pricing and reimbursement**
- **Key Components of Market Access**
 - **Regulatory approval**
 - **Health Technology Assessment (HTA)**
 - **Pricing and reimbursement negotiations**
 - **Patient access schemes**
- **Importance of Market Access**
 - **Timely** access to therapies
 - Financial **sustainability of healthcare systems**
 - **Competitive advantage** for pharmaceutical companies



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III. CHALLENGES IN MARKET ACCESS

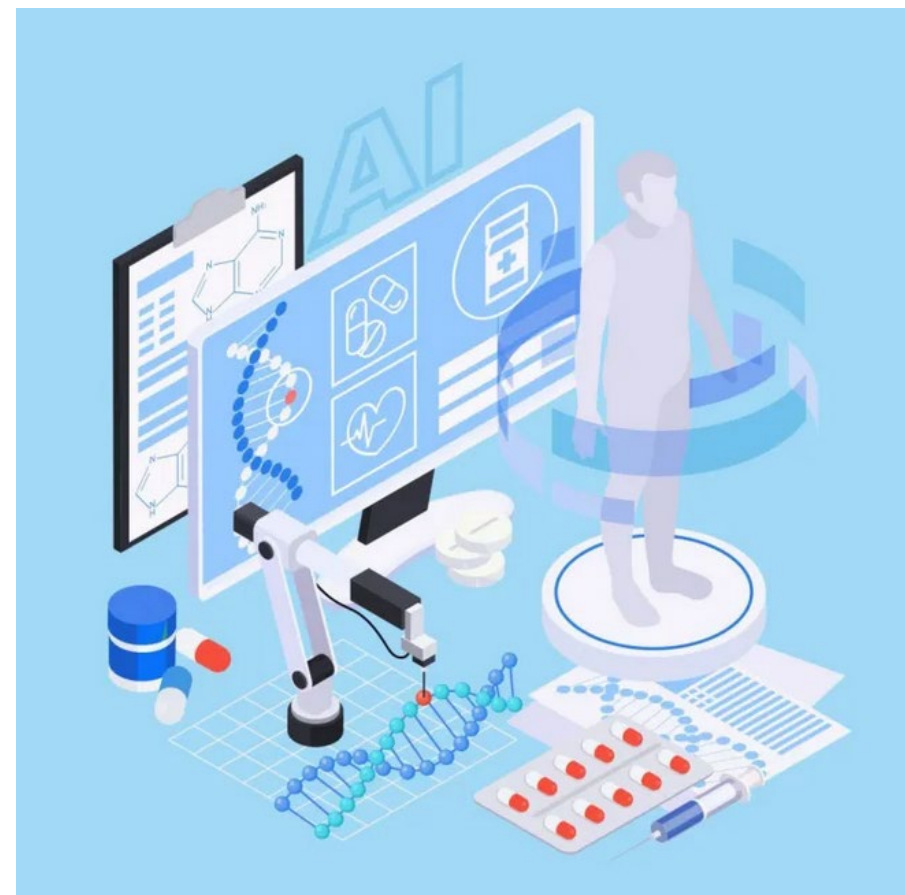
- Complex Regulatory Environments
- Variability in HTA Processes
- Long Timelines for Approval
- High Costs and Resource Intensiveness
- Need for Real-World Evidence



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IV. HOW AI ADDRESSES MARKET ACCESS CHALLENGES (EXAMPLES)

- **Enhancing Timing**
 - Analytics for **Regulatory Submissions**
 - **Accelerating HTA Processes**
- **Improving Predictability**
 - Machine Learning Models for **Outcome Prediction**
 - **Risk Mitigation** through Data Analysis
- **Optimizing Outcomes**
 - **Better acceptance of optimized submissions** through AI
 - **Real-World Data Integration**



Source: Marksman

V. AREAS OF MARKET ACCESS ENHANCED BY AI (EXAMPLES)

- **Regulatory Affairs**
 - Automated Document Submission and Review
 - Predictive Models for Approval Success
- **Health Technology Assessment (HTA)**
 - AI in Cost-Effectiveness Analysis
 - Evidence Synthesis
- **Pricing and Reimbursement**
 - Dynamic Pricing Models
 - AI-Driven Negotiation Support
- **Patient Access Programs**
 - Identifying Eligible Populations
 - Monitoring and **Adjusting Schemes**



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VI. ENHANCING MARKET ACCESS FOR DOCTORS AND STAKEHOLDERS

- **Role of Doctors and Stakeholders:**
 - **Supporting knowledge for Prescription Decisions**
 - Ensuring Optimal Patient Outcomes
- **AI Tools for Doctors:**
 - AI-Driven **Clinical Decision Support Systems**
 - Personalized Treatment Recommendations
- **Engaging Other Stakeholders:**
 - AI in Healthcare Provider Education
 - Data-Driven Communication Strategies



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VII. CASE STUDIES AND EXAMPLES

- **Example 1: AI in Regulatory Submissions**
- **Example 2: Machine Learning for HTA**
- **Example 3: AI in Pricing Strategy Optimization**
- **Example 4: Personalized Patient Access Programs**
- **Example 5: AI-Driven Clinical Decision Support for Doctors**



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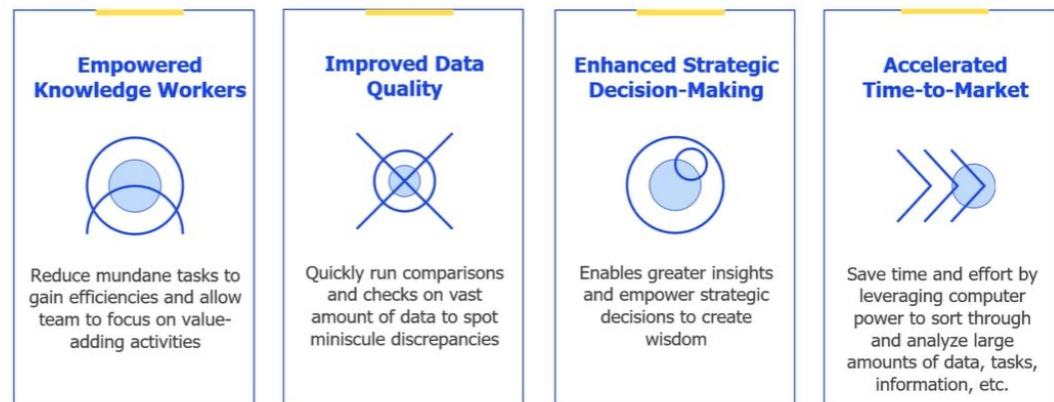
AI IN REGULATORY SUBMISSIONS

ArisGlobal:

- Provides end-to-end regulatory information management solutions*.
- Automates the submission process and compliance tracking.



What are potential benefits?



Specific capabilities and use cases



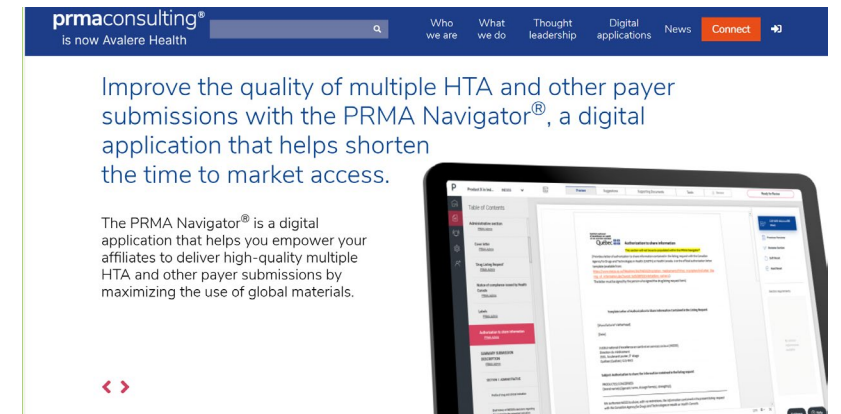
MACHINE LEARNING FOR HTA

■ PRMA Navigator®:

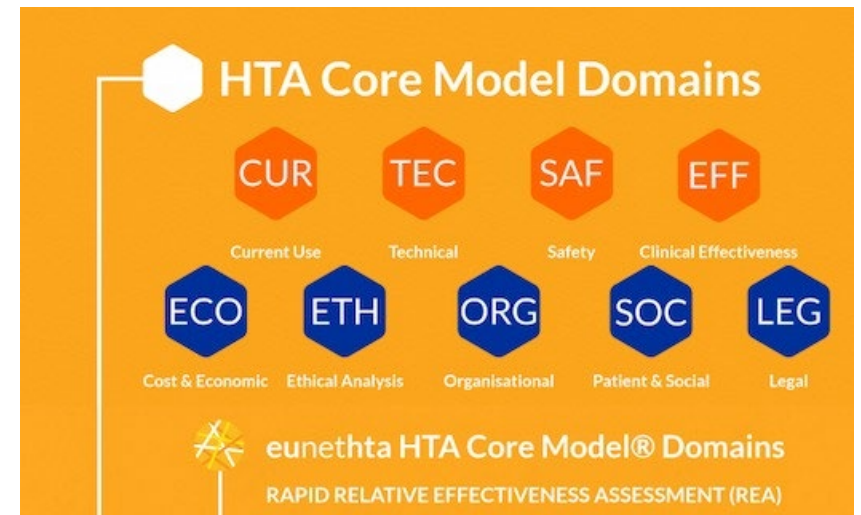
- An online platform that helps with HTA submissions.
- Uses AI to streamline and optimize the assessment process.

■ HTA Core Model® Online:

- Uses AI to support the development and dissemination of HTA reports.
- Facilitates the comparison of HTAs across different jurisdictions.

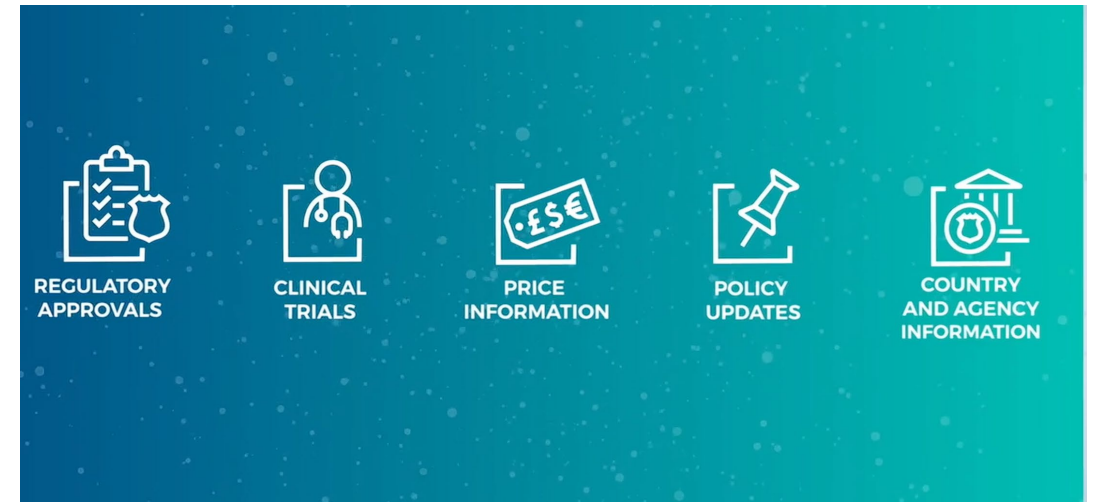


The screenshot shows the PRMA Navigator website. The header includes the logo "prmaconsulting® is now Avalere Health" and navigation links: "Who we are", "What we do", "Thought leadership", "Digital applications", "News", and "Connect". The main content area features a headline: "Improve the quality of multiple HTA and other payer submissions with the PRMA Navigator®, a digital application that helps shorten the time to market access." Below this is a sub-headline: "The PRMA Navigator® is a digital application that helps you empower your affiliates to deliver high-quality multiple HTA and other payer submissions by maximizing the use of global materials." To the right is an image of a tablet displaying the application interface. At the bottom left of the content area are two red arrows pointing left and right.



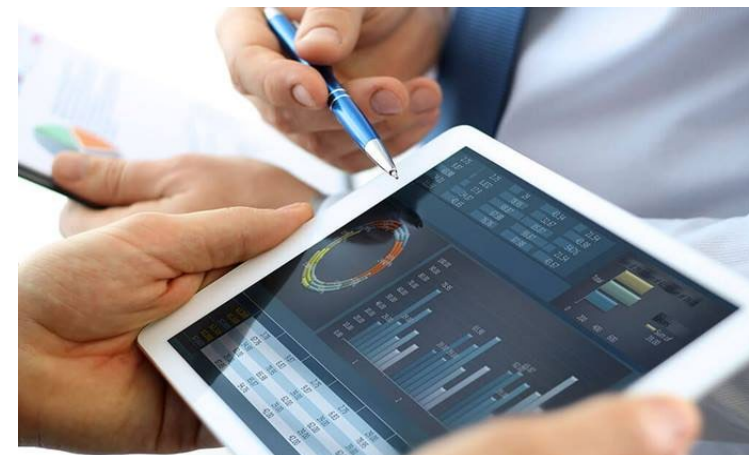
MACHINE LEARNING FOR HTA

- **Example: HTA Accelerator[®]**
- The Health Technology Assessment Accelerator (HTAA) from IQVIA allows the user to analyze past and current payer assessments and evidence requirements to guide clinical trial design and market access strategy across the product lifecycle.



AI IN PRICING STRATEGY OPTIMIZATION

- **IQVIA Pricing and Market Access:**
 - Leverages AI and advanced analytics for dynamic pricing models (eg. International Reference Pricing (IRP) Tool)
 - Supports negotiation strategies with payers and stakeholders.
- **PharmaPendium by Elsevier:**
 - Provides predictive analytics for drug pricing and reimbursement scenarios.
 - Integrates regulatory and scientific data to support pricing decisions.



PharmaPendium is the most powerful way to advance your drug portfolio

Find the best strategy for your drug candidates' safety and efficacy. Reduce animal testing. Go to market faster with safer life-transforming treatments for patients. Trusted by the FDA, PMDA and the world's top 20 pharma companies.

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The new PharmaPendium has enhanced visualization, intelligent autocomplete and search results that bridge the preclinical to clinical divide.

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AI IN PATIENT ACCESS PROGRAMS

- **Optum's Symmetry EBM Connect:**
 - Uses AI to identify eligible patient populations.
 - Supports the design and monitoring of patient access schemes.
- **Veradigm's Health Insights:**
 - Analyzes real-world data to support patient access programs.
 - Offers insights into patient adherence and outcomes.

Optum® Symmetry® EBM Connect® uses administrative data, laboratory results and non-claims electronic data to measure health care quality. EBM Connect software identifies gaps between clinical evidence and health care practice with applications for a variety of health care organizations. It captures substantial information about quality care measurement and compares actual, observed member care with care supported by sources such as clinical trials and national guidelines.



42M+
patients with linked EHR + **closed claims**

25M+
patients with linked EHR + **open claims***

PHYSICIAN NOTES
(unstructured data) available for **50M patients**,
for natural language processing (NLP) extraction

*5 Year Time Period: November 2015–October 2019

AI-DRIVEN CLINICAL DECISION SUPPORT FOR DOCTORS

- **Watson for Oncology by IBM:**
- Provides AI-driven clinical decision support for oncologists.
- Offers evidence-based treatment recommendations personalized for patients.
- **KAIT by University of Leipzig, ICCAS, Merantix and Janssen/J&J***
- Knowledge-Based and AI-Driven Platform for Therapy Decision-Support in Hematology

<https://kait.health/demo/case.php#>

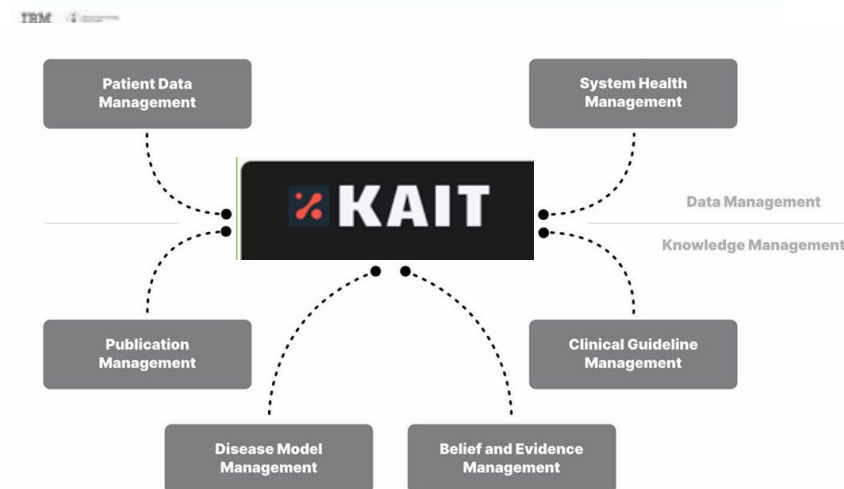
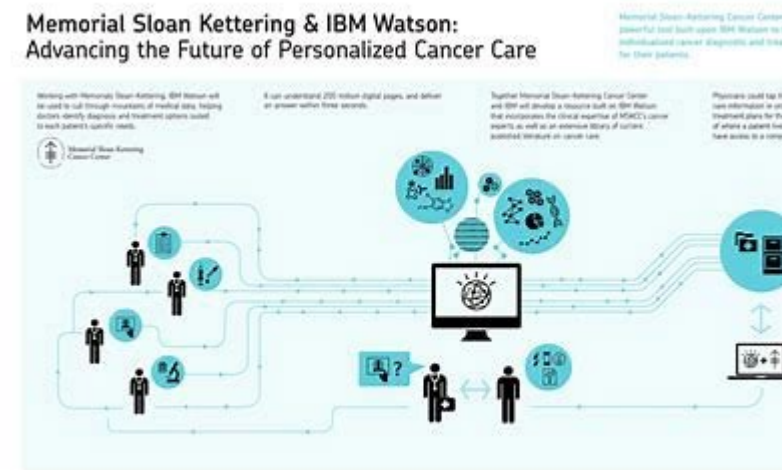


Figure 1 – Topology of KAIT's service-based architecture

Comparison of structured patient data with relevant publications



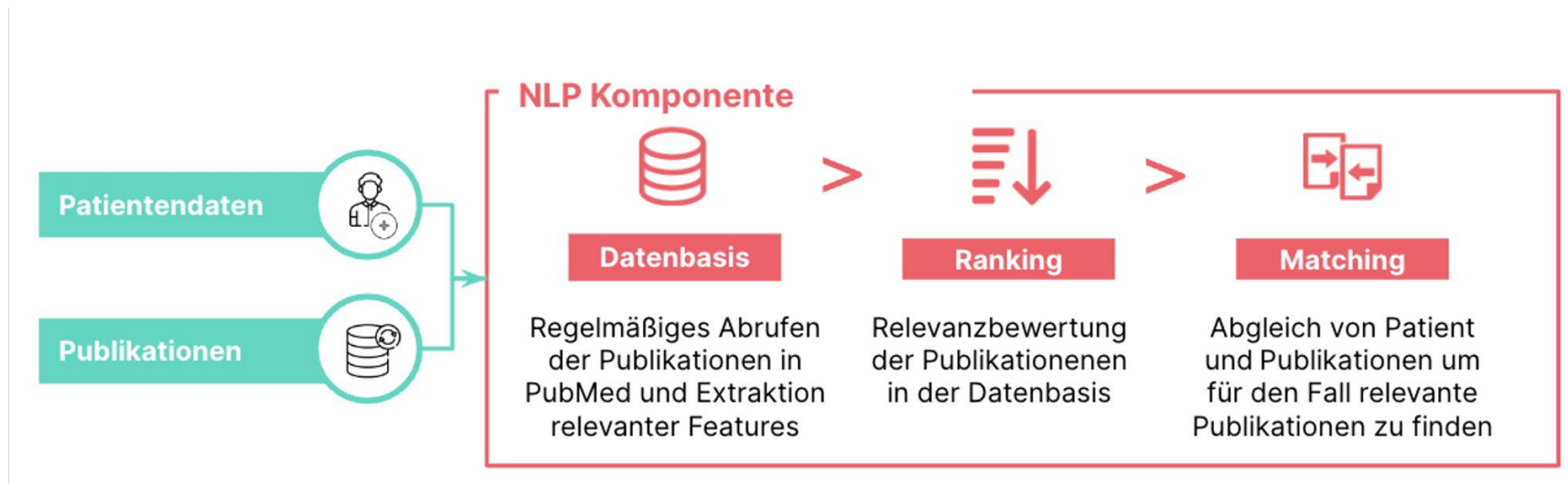
Goal Tailor-made treatments for heterogeneous hematological diseases and patients

Data

- Structured patient data
- Medical publications in PubMed

Added value

- Reduced reliance on physician experience and access to innovative therapies to make treatment decisions
- Enabling patient-specific and effective cancer treatment decisions
- More efficient literature research



AI-DRIVEN CLINICAL DECISION SUPPORT FOR DOCTORS

“The KAIT platform represents the most ambitious take on AI-assisted and completely traceable hematologic clinical decision-support to date. It will act as a comprehensive example of how the most recent advancements in the field of ML and AI can complement the daily clinical routine efficiently and sustainably.

KAIT is built with continuous growth and progress in mind. Thus, it will be our ubiquitous goal to ensure that its inherent benefits are accessible to as many users as possible to establish the most reliable and trustworthy platform for therapeutic decision-support and knowledge management in hematology”

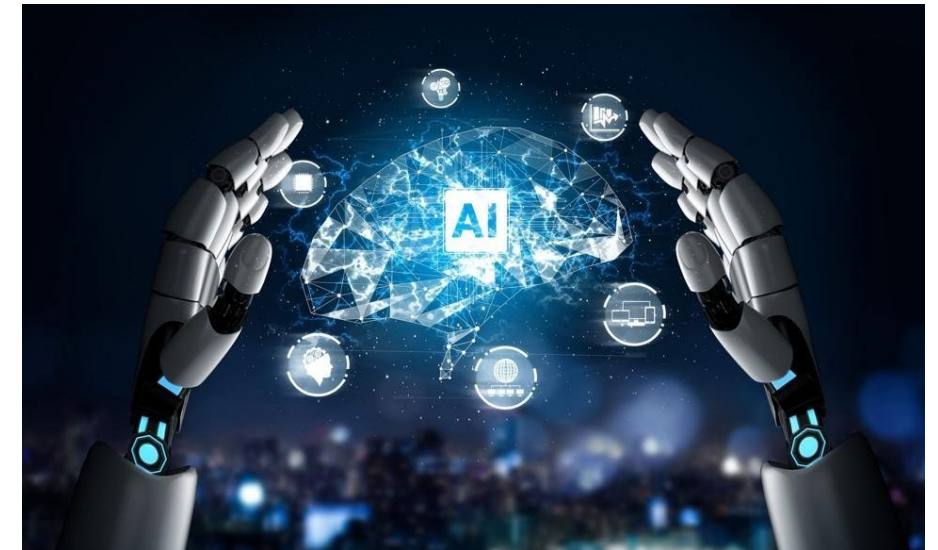
The screenshot displays the KAIT web application interface. At the top, the KAIT logo is on the left, and navigation links for 'Accountverwaltung', 'Feedback', and 'Hilfe' are on the right. A user profile for 'Demo User' is also visible. The main navigation bar includes 'Übersicht', 'Patienten', and 'Meetings'. Below this, a search bar for 'Patient suchen...' is present, along with status indicators for 'Patienten in Behandlung' and '3 Patienten in Remission'. A 'Filter' section on the left allows for filtering by 'Krankheitsbild', 'Therapielinie', and 'Patientenstatus', with a 'Neue Fallakte anlegen' button below. The main content area shows a list of patient records, including details for 'Padmé Amidala' and 'Lando Calrissian', such as their IDs, birth dates, and current treatment status (e.g., 'Multipl. Myelom - IgM Lambda', 'derzeit in Behandlung').

AREAS OF INTEREST JNJ INNOVATION DATA SCIENCE

- Drug Discovery: **AI & Machine Learning (ML)** to drive:
 - High-value biological insights & targets
 - Reduced cycle time & improved NME quality
- Drug Development: **AI & ML** to drive:
 - Improved clinical trial design, including early detection, better endpoints & patient stratification
 - Accelerated clinical trial operations
 - Enhanced Diversity & Inclusion
- Regulatory submissions & internal decisions: **Real-World Evidence (RWE) & external control arms** for augmentation
- Digital health & treatments, Software as a Medical Device & decentralized trials to enhance care

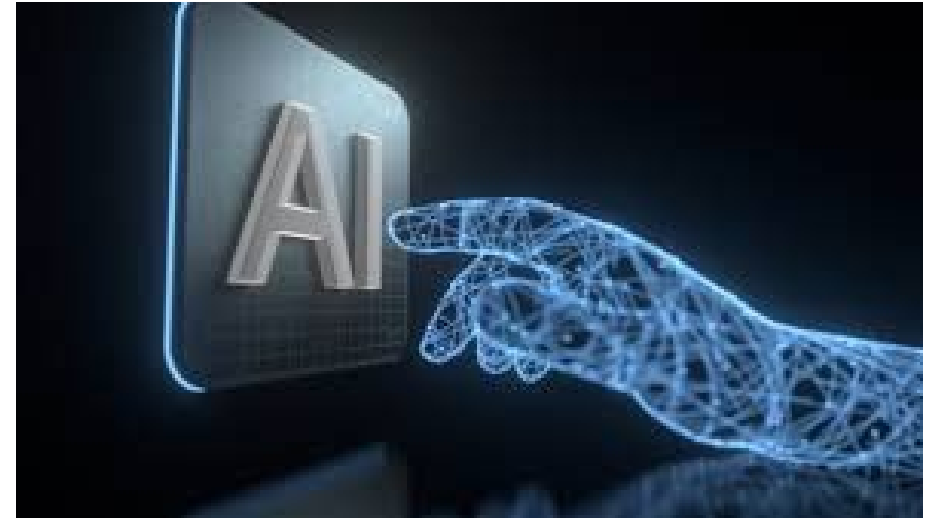
FUTURE OUTLOOK FOR AI IN MARKET ACCESS

- **Continuous Innovation:**
 - Expect more sophisticated AI tools that integrate multiple facets of market access.
- **Increased Adoption:**
 - Greater acceptance and use of AI by regulatory bodies and healthcare providers.
- **Collaborative Ecosystem:**
 - Enhanced collaboration between pharma companies, regulators, payers, providers, and patients through AI.



FUTURE OUTLOOK FOR AI IN MARKET ACCESS – PEOPLE NEEDS

- **Skill Development needed:**
 - Need for proficiency in AI and data analytics.
 - Roles in IT, Quality and Regulatory
- **Strategic Roles shifted:**
 - Shift towards data-driven decision-making and strategy formulation.





THANK YOU!

HAPPY TO
ANSWER
QUESTIONS
DURING
THE BREAK!