



DITTA GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT & RADIATION THERAPY
TRADE ASSOCIATION



IMDRF International Medical
Device Regulators Forum

IMDRF / DITTA joint workshop

Artificial Intelligence in Healthcare *Opportunities and Challenges*

Monday, 16 Sept. 2019, Yekaterinburg

AI in Healthcare & Regulatory Developments (An Industry Perspective)

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- Concrete examples by industry of AI software in different application areas
- What does AI bring to healthcare from a clinician's perspective
- Development of AI based software causes both new opportunities as well as new challenges



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INTRODUCTION INTO AI...

- Terminology is still to be defined globally
 - Artificial Intelligence, Machine Learning
 - Learning – Supervised, Unsupervised
 - Locked/Unlocked Algorithms – Discontinuous/Continuous Learning
- Standards & Regulatory requirements are still being defined globally
 - AAMI, BSI, ISO, USA FDA, AMA, CHI, Xavier University, DITTA/MITA, etc.
- Clinical Utility (incl. acceptance/adoption) is still being defined globally
- Reimbursement/Payment varies by country
- Entry by non-traditional medical device mfg. – Apple, Google, etc.



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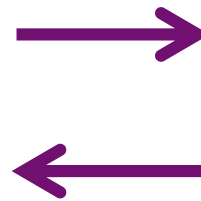
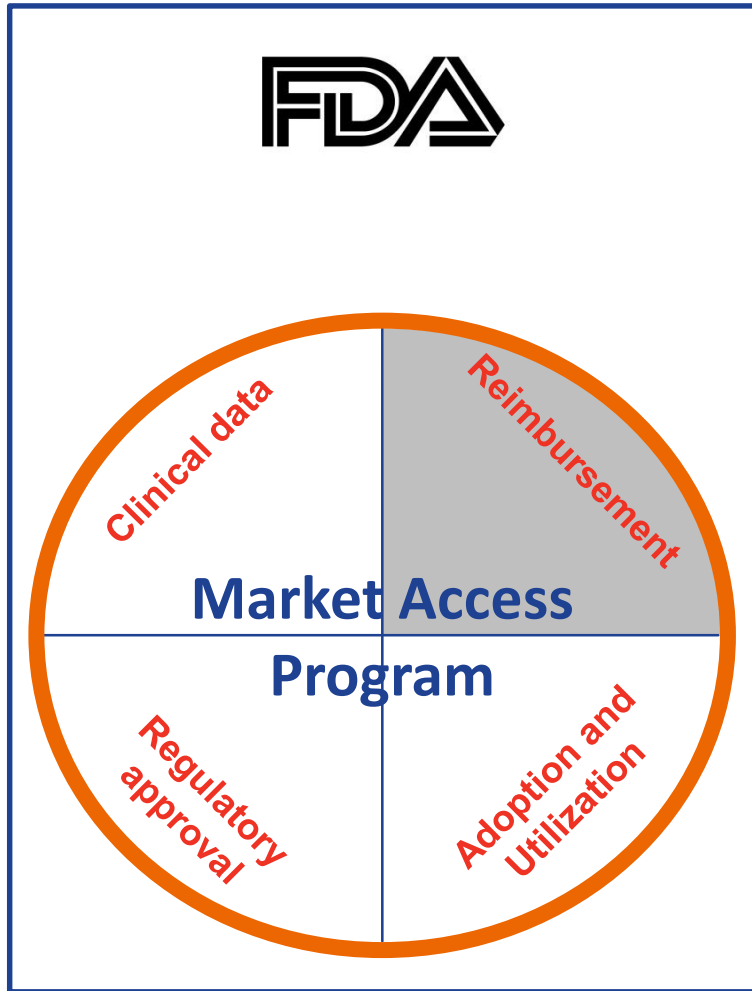
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EXAMPLE: USA





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CONCRETE EXAMPLES BY INDUSTRY OF AI SOFTWARE IN DIFFERENT APPLICATION AREAS...

- AI application & relevant medical discipline vary...
- Monitoring (many smartphone enabled)
 - Apple: A-fib detection
 - Empatica: Epilepsy detection
 - AliveCor: ECG
- Triage
 - IDx: Diabetic retinopathy referral
 - Viz.ai: Stroke detection referral
- Clinical Decision Support
 - Arterys: Liver & lung cancer diagnosis
 - Aidoc: Pulmonary embolism diagnosis



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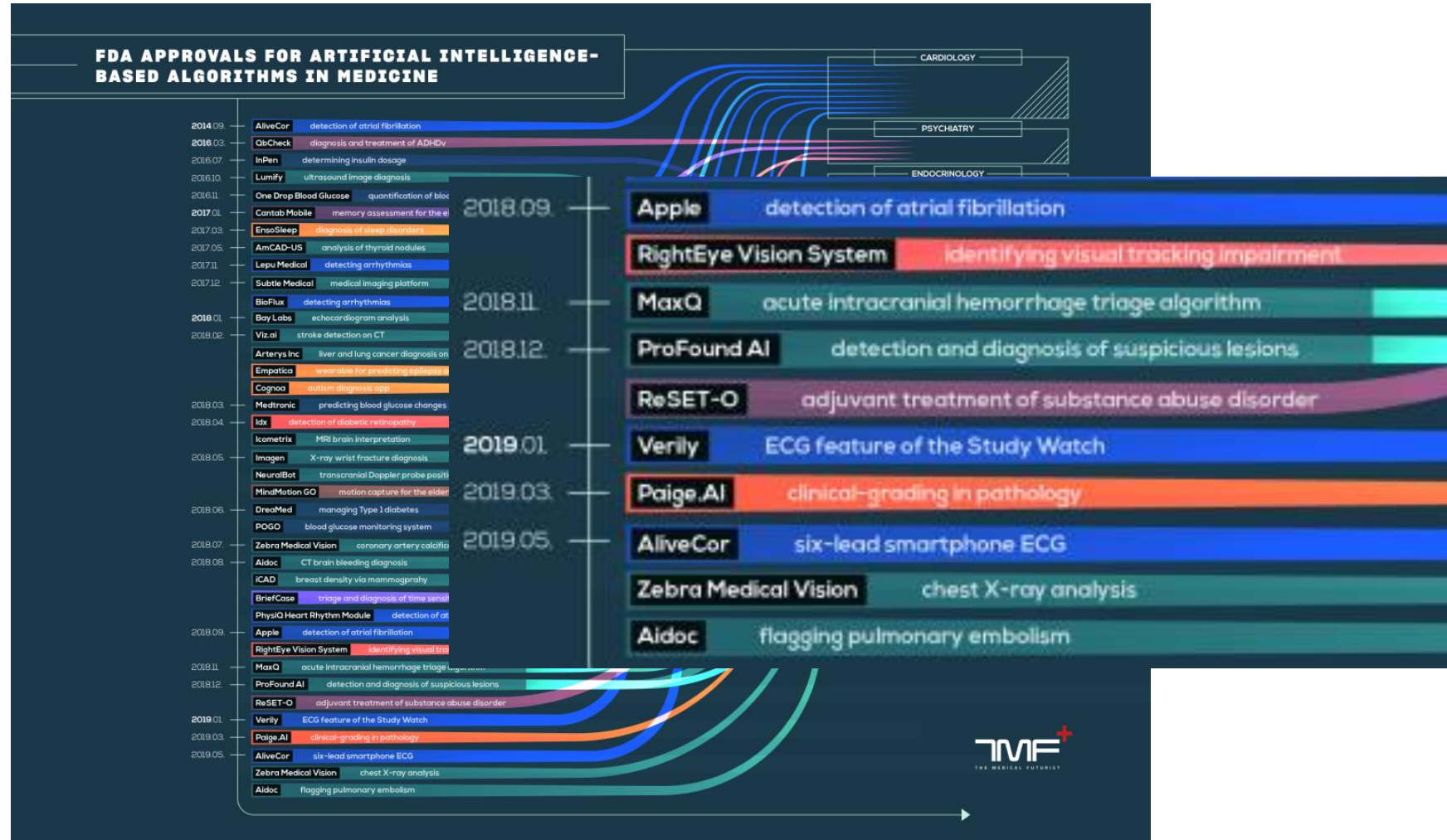
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WHAT DOES AI BRING TO HEALTHCARE FROM A CLINICIAN'S PERSPECTIVE...

- Better integration of clinical data
- Aid in monitoring, triage, clinical decision support
- Improved clinical outcomes
- Enhanced resource management – clinician fatigue/burnout, availability, specialization, etc....
- Simply put, AI can be leveraged to augment:
 - Repetitive & creative activities
 - Highly interactive & data-driven activities



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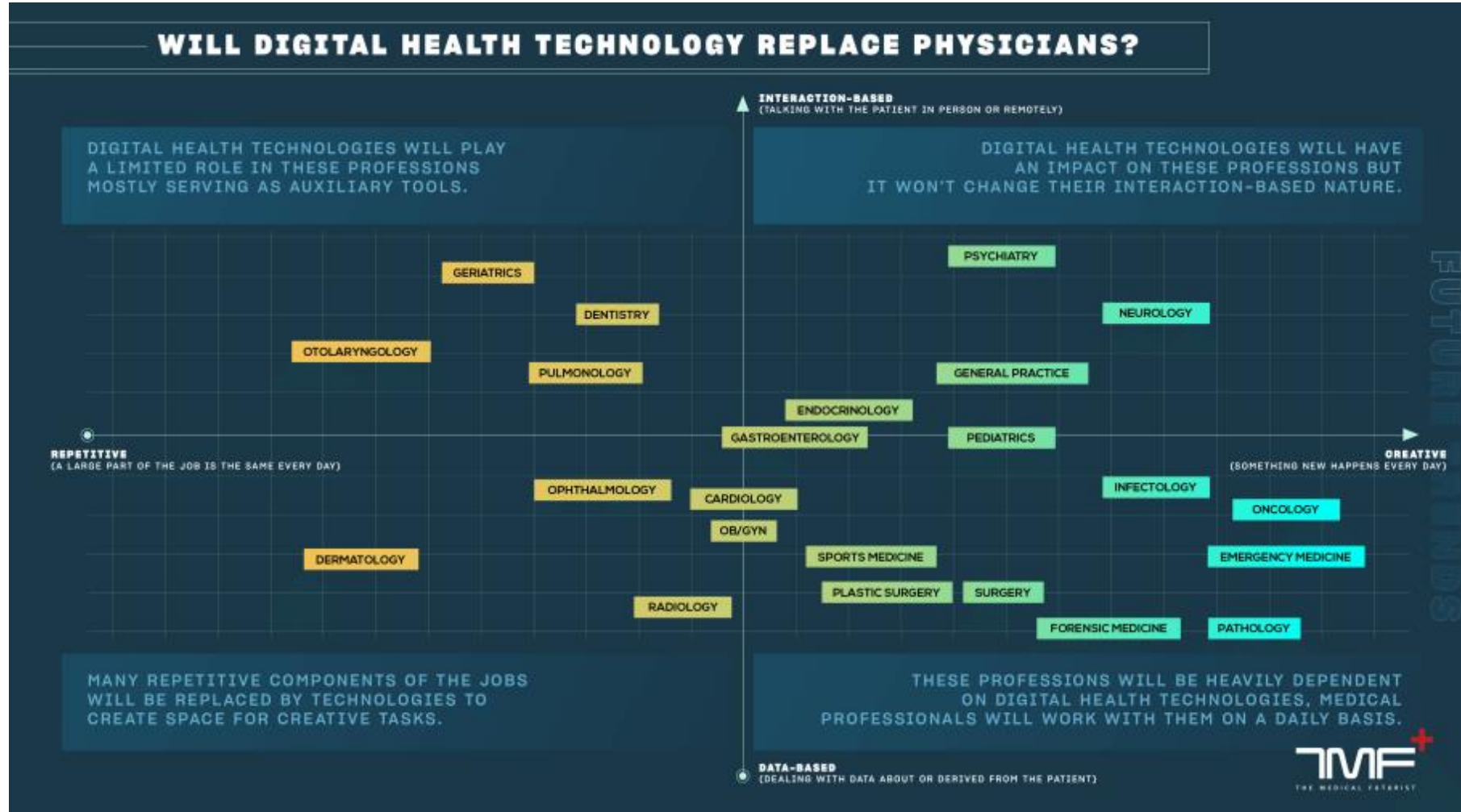
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DEVELOPMENT OF AI BASED SOFTWARE CAUSES BOTH
NEW OPPORTUNITIES AS WELL AS NEW CHALLENGES...

Opportunities:

- Improved clinical outcomes
- Aid in monitoring, triage, clinical decision support
- Better integration of clinical data

- Meets all of the goals of the Quadruple Aim
 - Improving the patient experience (incl. prevention of loss of health, satisfaction with care)
 - Improving the health of populations
 - Reducing the cost of healthcare
 - Improving the Clinical Providers experience (incl. clinicians, nurses, technologists, etc.)



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DEVELOPMENT OF AI BASED SOFTWARE CAUSES BOTH
NEW OPPORTUNITIES AS WELL AS NEW CHALLENGES...

Challenges:

- AI-dependent
 - Explainability/Explicability
 - Transparency
 - Trustworthiness
- Industry/Regulatory
 - Aligning terminology
 - Nascent standards & regulations
 - Developing clinical evidence requirements
 - Integrating Risk into R&D & regulatory activities (incl. autonomy-driven concerns)
 - Commercialization processes need multiple/branched pathways sensitive to risk (based on Risk, e.g. autonomy)



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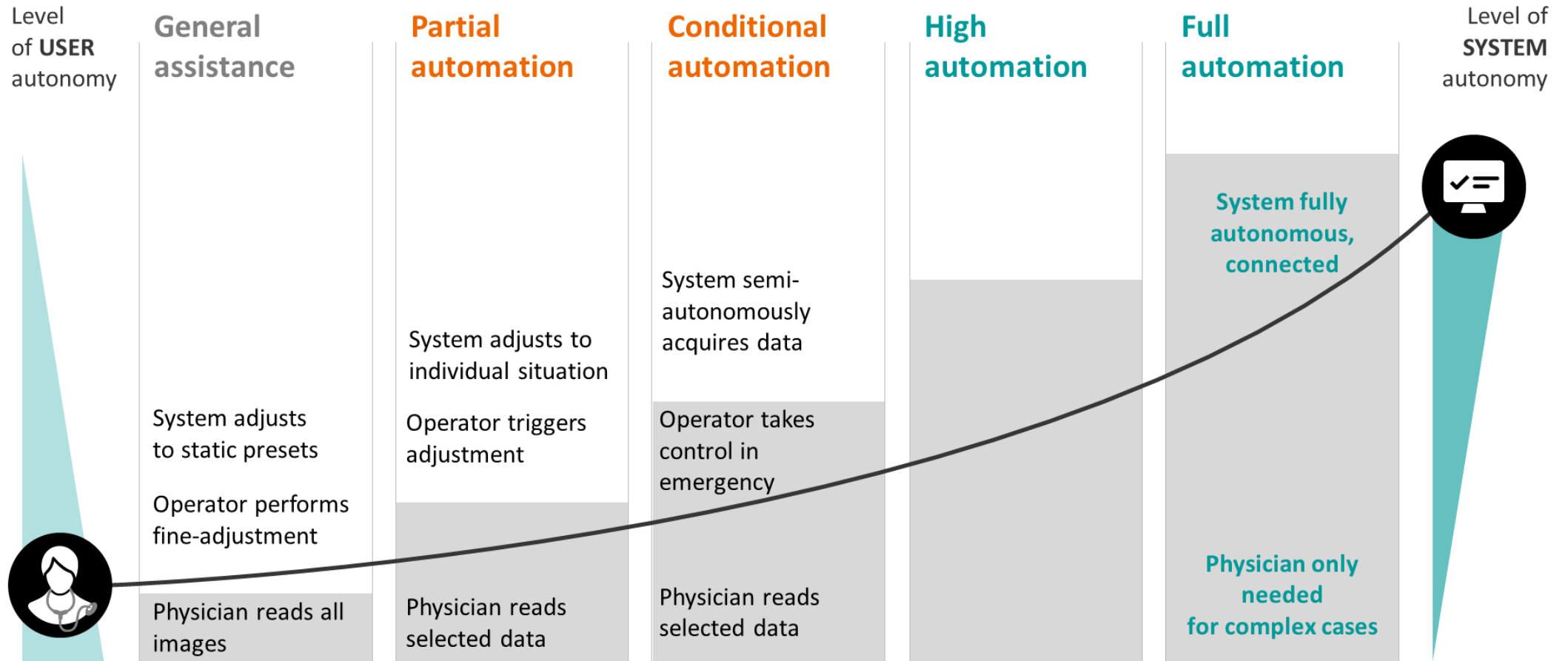
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AI KEY TAKEAWAYS...

- Much is still yet to be defined & implemented
- Many key aspects to commercialization & adoption remain to be addressed:
 - Right-sizing requirements to Risk (patient, clinician, etc.)
 - Aspects of Explainability/Explicability, Transparency, Trustworthiness, etc.
 - And last, determining how to reimburse/pay manufacturers for R&D & products – purchase vs. pay for use models
- International convergence of regulatory approaches is needed



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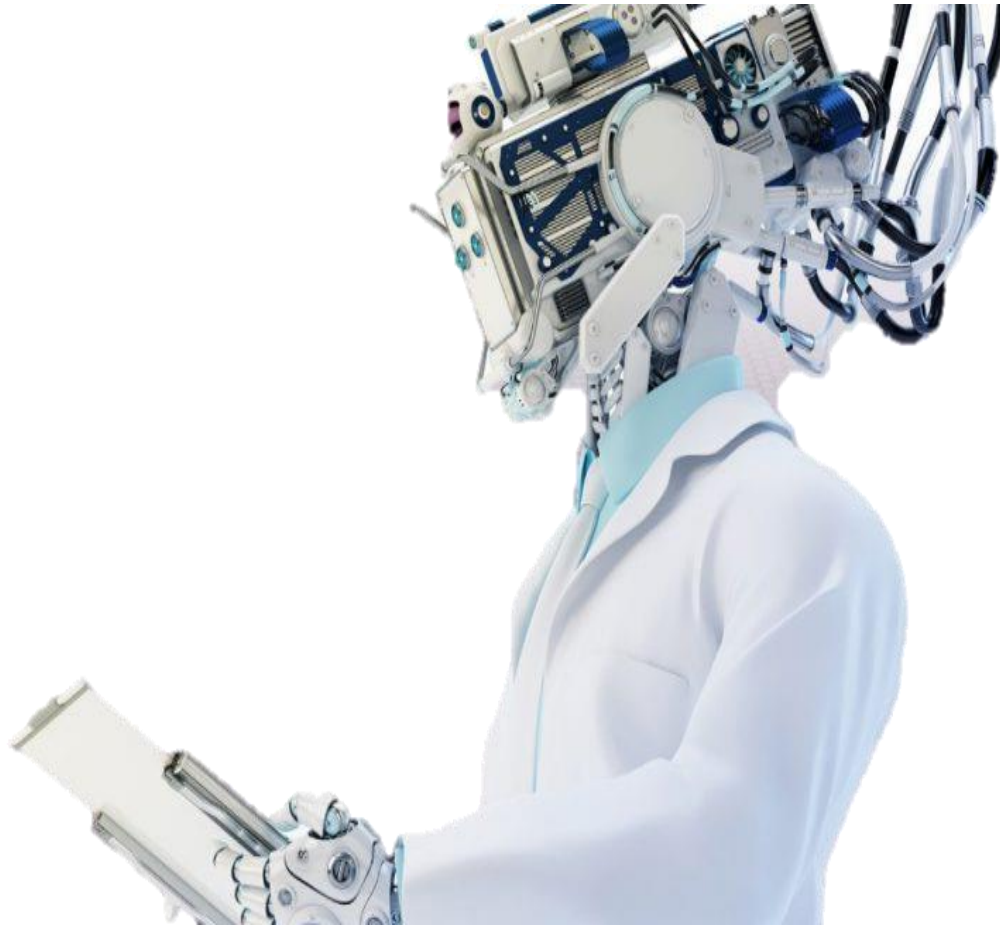
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The Doctor will see you now...





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Thank you!
Спасибо!

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