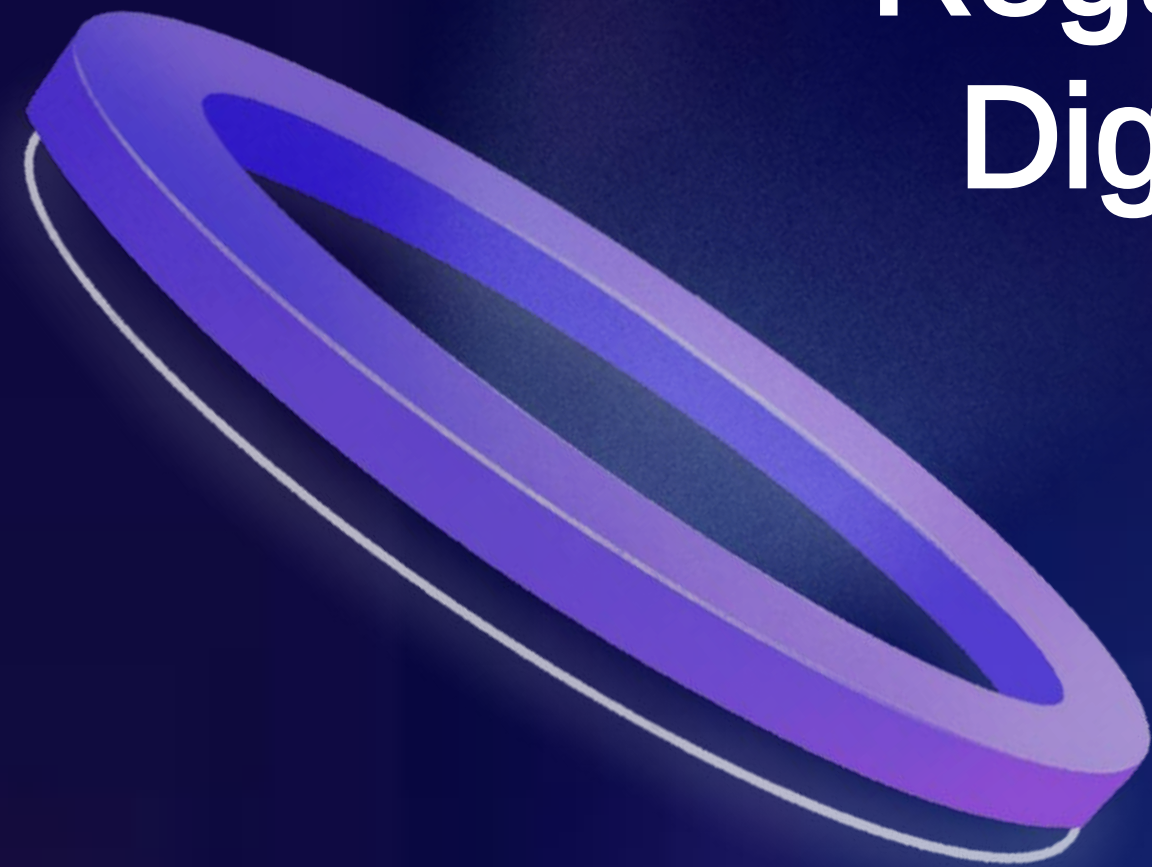


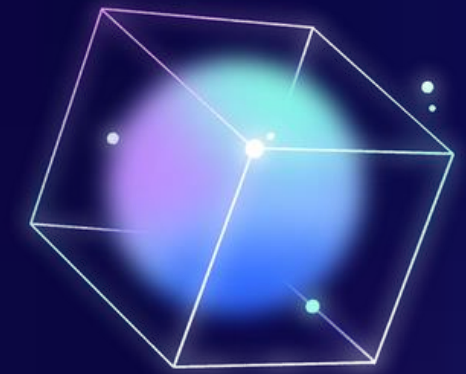
**Option 1:**  
**Looking through the**  
**Cristal Ball:**  
**Technological &**  
**Regulatory Future of**  
**Digital Healthcare**

**Option 2:**  
**Healthcare**  
**Stand-up**

**Moshe Klaiman**  
**Matrix Medika**  
**19.3.2024**

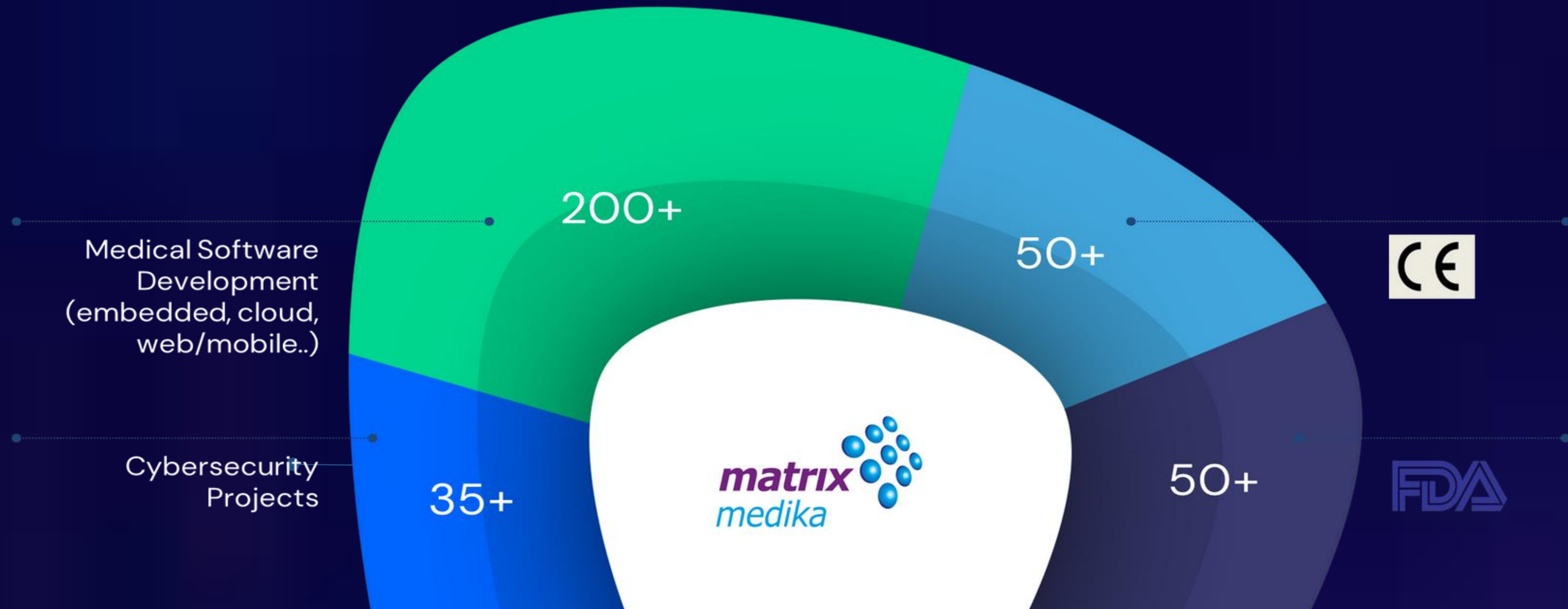


# A few words about Matrix Medika





Matrix Medika- Israel's leading provider of software development, regulation and cyber security services for the healthcare industry





## IDA - Intelligent Dialysis Assistant



## Remote Medical Team



NEPHRO CARE Powered by iRenDi Activated devices 45 Activated Clinics 340 Total No. of exchanges 35,675 Dr. Ronit Shahar [Log Out](#)

DEVICES USERS SETTINGS PATIENT LIST ADD PATIENT

← **Salma Fonseca** 031223345 | 60 years | Female EXCHANGES VISITS PRESCRIPTION PROFILE

Filter by date  Filter by status

Date & Time	Status	Drain duration min	Drain volume ml	Drain temp °C	Fill volume ml	Fill temp °C	Weight kg	Target weight kg	Blood pressure mmHg	Pulse bpm	Turbidity	UF ml	Notes
5 Mar 19   22:00	●	17	2350	36.8	2000	37.5	81.8	79			51	350	
5 Mar 19   17:10	● Exchange skip										49		
5 Mar 19   11:40	●	16	2050	36.9	2000	37.4					48	50	
4 Mar 19   06:12	●	16	2100	37.0	2000	37.1					50	100	
4 Mar 19   22:45	● Increase weight	17	2050	36.9	2000	37.3	82.5	79	110/90	72	52	50	
Comment <span>4 mar 16:22</span>													
<input type="text" value="Decreased urine output. Prescription Changed"/>													
4 Mar 19	●	16	2150	36.8	2000	37.2		79			48	150	
4 Mar 19   12:00	●	16	2250	36.9	2000	37.1		79			48	250	
4 Mar 19   5:55	●	15	2150	37.0	2000	37.4		79			52	150	

← 1 2 3 →

iRen is the **world's first** all-in-one Digital Dialysis Clinic, allowing people treated for kidney disease to perform Peritoneal Dialysis anywhere, safely, simply and effectively!





### Body temperature

00.0 °C

Place the lower end of the thermometer base between the eyebrows, the lower end of the stethoscope on the forehead.

### Heart rate & saturation

Progressing indicator

Cover the sensor gently with your thumb  
Don't press or hover. Keep calm and stable.

### Heart

Right Left

Position stethoscope on point "A"  
Click the activation button to record

### Left Ear

Take video

### Throat

Pharynx  
Take video

### Skin

Add from library  
Take a photo of the skin

## NONAGON

### Choose Where & When To Receive Care

Using a convenient device paired with your smartphone, you can conduct 9 medical-grade physical exams whenever and wherever you want.  
Giving the doctor the information they need to make a data based diagnosis isn't just better for the doctor, it's better for everyone.

[Learn More](#)

Johanna Olson

Live Session

Saturation & Pulse

97% 75 bpm

End Exam

Export Data Save & Update

Johanna Olson

Live Session

Heart

Point A  
Point B  
Point C: Press record when ready

End Exam

Export Data Save & Update

**DISPOSABLE SAMPLER**

For sample collection and prep



**DESKTOP SCANNER**

For easy operation and labor delegation



**WEB APPLICATION**

User interface



**AI IMAGE ANALYSIS**

Immediate multicausal, suggested diagnosis

Deep Learning in the cloud, based on a unique classified image archive

Test Date & Time  
**14 Nov 2018 11:25**

PH  
**5**

GYNI Diagnosis 1  
**Bacterial Vaginosis**

GYNI Diagnosis 2  
**Bacterial Vaginosis**

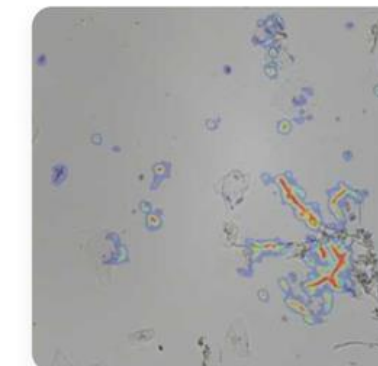
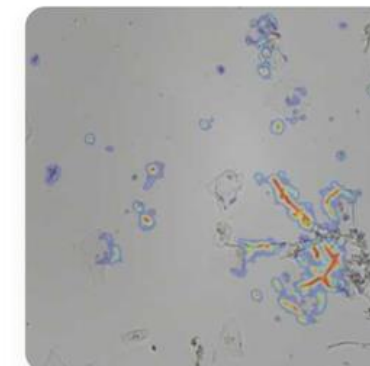
GYNI Diagnosis 3  
**Bacterial Vaginosis**

Patient YOB  
**1982 (39 yo)**

Complaints

Burning

Discharge





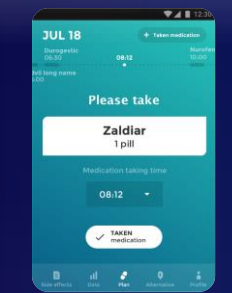


NAME OF THE PROTOCOL

FIXED TIME MEDICATION

TIME SLOT	MEDICATION	DOSE	MAX DAILY DOSE	ACTIVE INCIDENT DAILY LIMIT
08:00	Phenacetin	500 mg	3000 mg	Chlorzoxazone 800 mg
12:00	Opaxodin	500 mg	3000 mg	Chlorzoxazone 800 mg
16:00	Zaldiar	50 mg	300 mg	Chlorzoxazone 800 mg

ADDITIONAL MEDICATIONS



# Regulation, Cybersecurity, Privacy



FDA submissions

CE submissions

IEC 62304 compliance

## Cyber Security & Compliance

- Compliance assessment (per FDA and CE guidance)
- Penetration Testing
- FDA/CE Cyber Report

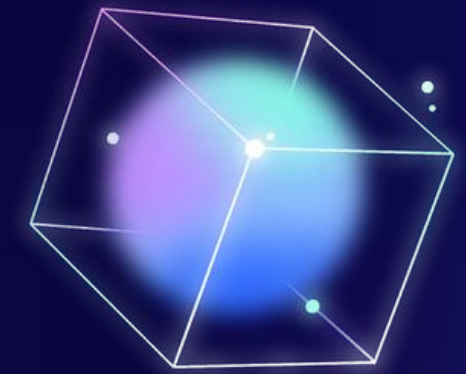
## HIPAA, GDPR Compliance

- Compliance assessment and Gap analysis in product and company level
- Company adoption (procedures, terms & conditions, training)

ISO 27001 \ 27799 \ 27017



Prediction is very difficult,  
especially if it's about the future



either

Niels Bohr, Nobel laureate in Physics and father of the  
atomic model

or

famous baseball player, Yogi Berra

## Healthcare trends 2010 till today

- Electronic Health Records
- Telehealth and Telemedicine
- Wearable Devices and Remote Monitoring
- Artificial Intelligence (AI) in Healthcare
- Precision Medicine
- Health Information Exchange (HIE)
- Robotics and Automation
- Blockchain in Healthcare
- 3D Printing in Healthcare



## The Top 5 Healthcare Trends In 2023



**Artificial  
Intelligence in  
Healthcare**



**Remote Healthcare -  
Virtual Hospitals,  
Healthcare  
Communities, and  
Telehealth**



**Wearable Medical  
Devices**



**Personalized  
Healthcare**



**Retail  
Healthcare**

## Gartner's Top Strategic Technology Trends for 2023



### Optimize



### Scale



### Pioneer


 Digital Immune System	 Industry Cloud Platforms	 Superapps
 Applied Observability	 Platform Engineering	 Adaptive AI
 AI TRISM	 Wireless-Value Realization	 Metaverse
 Sustainable Technology		



# Top 100 medical and healthcare startups in Israel


Updated June 18 2023

**1 Novocure**




Funding: **\$903.5M**  
 Novocure is an oncology company pioneering a novel therapy for solid tumors called Tumor Treating Fields, or TTFs. TTFs are low intensity, alternating electric fields within the intermediate frequency range. TTFs disrupt cell division through physical interactions with key molecules during mitosis. This non-invasive treatment targets solid tumors.

**2 NanoX Medical**




Funding: **\$274M**  
 Nanox Medical researches and develops breakthrough X-ray technology that generates unique monochromatic X-rays with very high fluency.

**3 Aidoc**




Funding: **\$237.5M**  
 Aidoc helps radiologists work through their case load faster, just in time to make a difference. We reworked deep learning algorithms to analyze imaging and clinical data more effectively, and can produce highly accurate scan anomaly detection. We combine the analyzed scans with patient data, streamlining the radiologists' workflow and freeing them to do what they do best.

**7 EarlySense**




Funding: **\$145M**  
 EarlySense develops signal-processing technology, offers EverOn, a contact-free and early detection patient supervision system.

**8 OrCam**




Funding: **\$130M**  
 OrCam's mission is to harness the power of artificial vision by incorporating pioneering technology into a wearable platform which improves the lives of individuals who are blind, visually impaired, and have reading difficulties. OrCam has created a technologically advanced device unique in its ability to provide visual aid through a discreet wearable platform and simple easy-to-use interface which serves to enhance the daily lives of people with vision loss.

**9 Memic**




Funding: **\$128M**  
 Memic has set out to transform robotic-assisted surgery, with proprietary technology that has the potential to far surpasses today's best solutions. Providing unprecedented access and maneuverability, our Memic's Hominis surgical platform features miniature, humanoid-shaped robotic arms with human dexterity, superhuman flexibility, and 360° articulation.

**4 ReWalk Robotics**




Funding: **\$210.6M**  
 ReWalk Robotics is an innovative medical device company that is designing, developing and commercializing exoskeletons allowing wheelchair-bound individuals to stand and walk once again. Our mission is to fundamentally change the Quality of Life for individuals with lower limb disability through the creation and development of market leading robotic technologies.

**5 Healthy.io**



Funding: **\$185M**  
 Healthy.io de Dip.io, a home-based urinalysis kit that turns a smartphone into a clinical-grade diagnostic device. It's the first smartphone-based urine test to secure clearance as a Class 2 device.

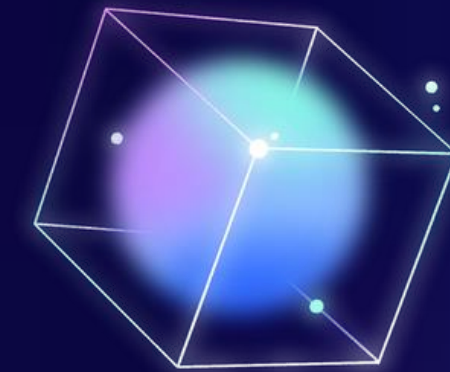
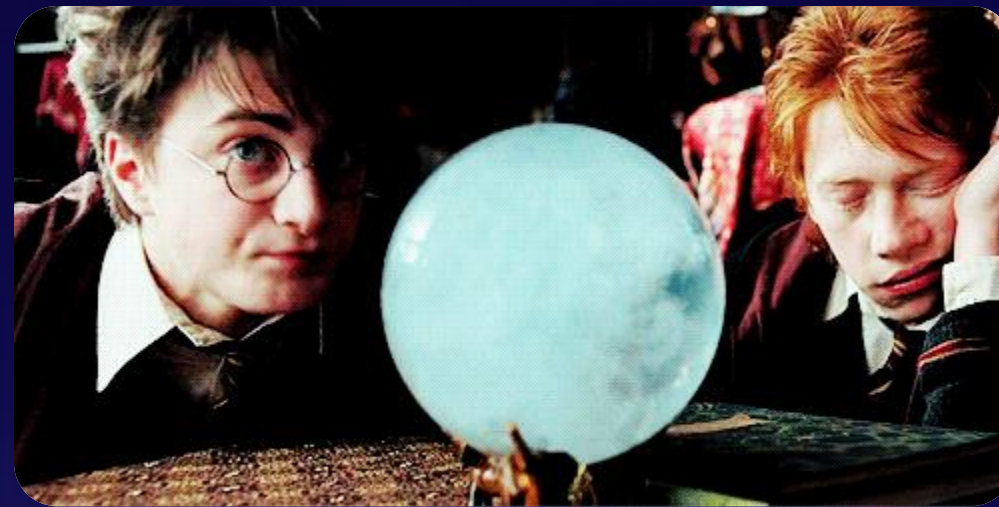
**6 TytoCare**



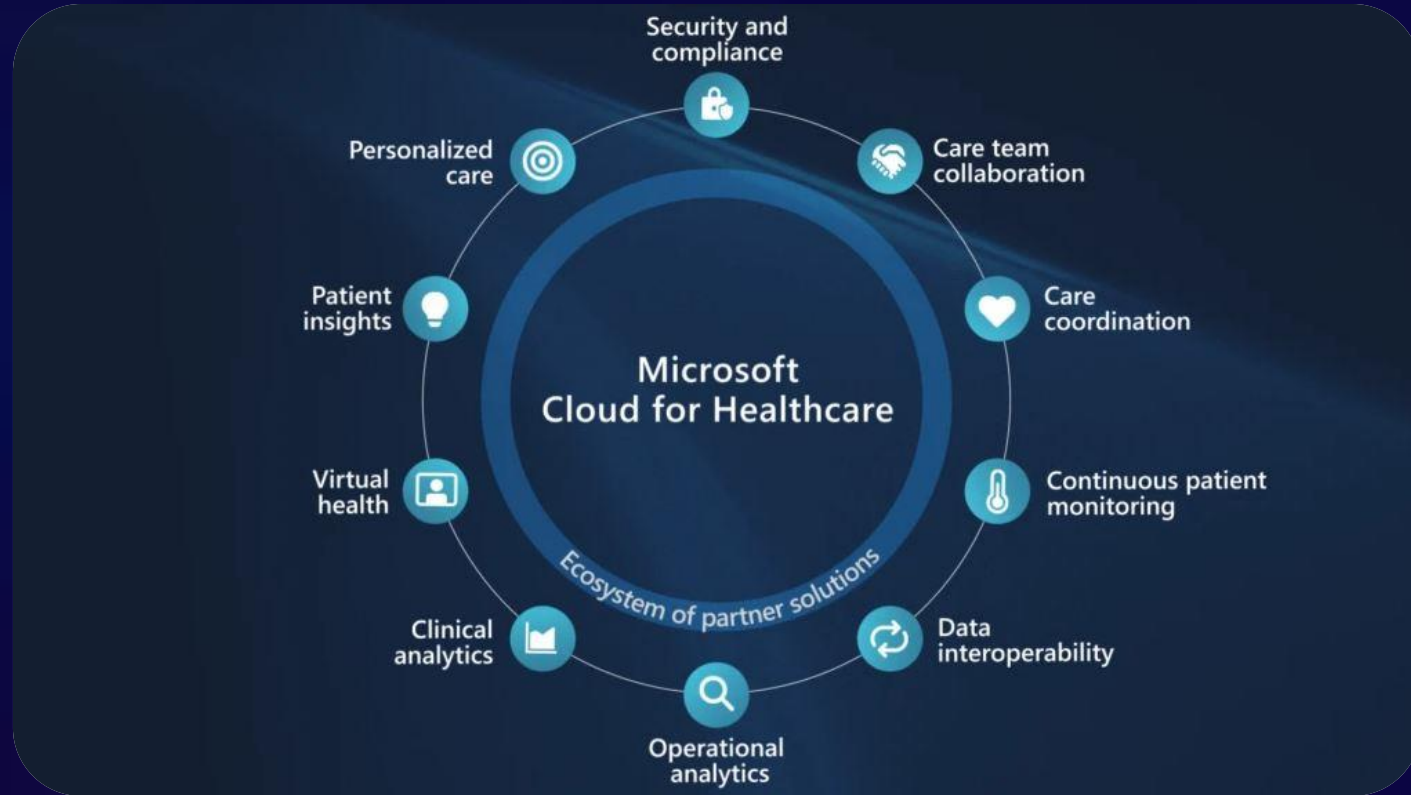
Funding: **\$156.7M**  
 A disruptive mobile-health platform and device, allowing anyone to perform self physical examination and remote diagnosis.



So... Let's take a look







## Azure OpenAI Top Capabilities and Use Cases

<p><b>Content generation</b></p> <p>Call center analytics: automatically generate responses to customer inquiries</p> <p>Generate personalized UI for your website</p>	<p><b>Summarization</b></p> <p>Call center analytics: summary of customer support conversation logs</p> <p><b>Subject matter expert document:</b> summarization (e.g. Financial reporting, analyst articles)</p> <p>Social media trends summarization</p>	<p><b>Code generation</b></p> <p>Convert natural language to SQL (or vice versa) for telemetry data</p> <p>Convert natural language to query proprietary data models</p> <p>Code documentation</p>	<p><b>Semantic search</b></p> <p>Search reviews for a specific product/service</p> <p>Information discovery and knowledge mining</p>
--	---	--	--

### Examples of multiple model use cases

- End to end call center analytics:** classification, sentiment, entity extraction, summarization and email generation
- Customer 360:** hyper-personalisation using timely summarization of customer queries & trends, search, and content generation
- Business process automation:** search through structured & unstructured documentation, generate code to query data models, content generation

### Explore AWS for Health solutions

<p><b>Healthcare solutions</b></p> <p>Take advantage of purpose-built solutions to transform healthcare.</p> <p><a href="#">View solutions »</a></p>	<p><b>Life sciences solutions</b></p> <p>Discover life sciences solutions that help you bring therapeutics to market faster.</p> <p><a href="#">View solutions »</a></p>	<p><b>Genomics solutions</b></p> <p>Make breakthroughs happen with genomics solutions that unlock insights.</p> <p><a href="#">View solutions »</a></p>
--	--	---

<p><a href="#">Clinical systems »</a></p>	<p><a href="#">Analytics &amp; AI / ML »</a></p>	<p><a href="#">Patient and clinician experience »</a></p>
<p><a href="#">Medical research »</a></p>	<p><a href="#">Finance and operations »</a></p>	<p><a href="#">Core health IT »</a></p>



Research and Engineering Studio

Sirius Cybernetics < RES > Home > Virtual Desktops

Virtual Desktops

All Windows Linux Launch New Virtual Desktop

adminuser1aml21 Stopped Amazon Linux 2 m6a.large No Schedule

rhel9-session Ready Redhat Enterprise Linux 9 t3.medium No Schedule

test-lin01 Stopped Amazon Linux 2 g5.xlarge No Schedule

test-win01 Ready Windows m5a.xlarge No Schedule

Actions menu: Connect, Session Permissions, Show Info, Schedule, Update Session, Virtual Desktop State (Start, Stop, Reboot, Terminate)

Research and Engineering Studio

Sirius Cybernetics < RES > Environment > Projects

Create new Project

Title: Total perspective vortex

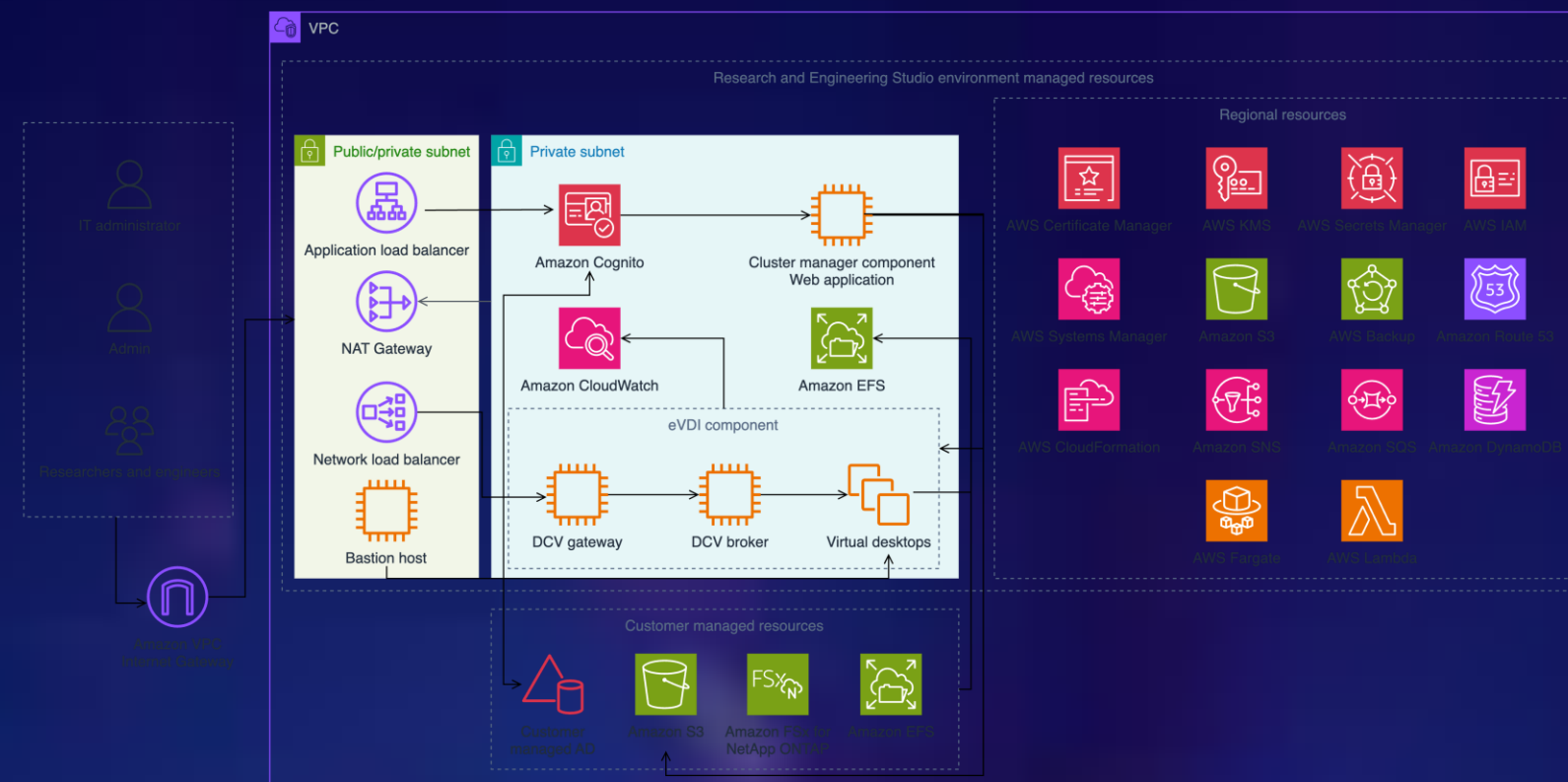
Project ID: zz9pluralalpha

Description: Simulation of the entire universe from a bread crumb

Groups: Astrophysics Group (1010)

Add file systems: home [efs], software [efs]

Submit





1. **Medical Imaging:** Generate synthetic medical images that closely resemble real patient data. This can be valuable for training and evaluating imaging algorithms
2. **Data Augmentation:** Augment existing medical datasets by generating new synthetic samples. This is particularly useful when the available data is limited or when privacy concerns restrict data sharing.
3. **Drug Discovery:** Generation of new molecules with desired properties for drug discovery.
4. **Synthetic Patient Data:** Generate synthetic patient data while preserving privacy and confidentiality.
5. **Personalized Medicine:** Generating individualized treatment plans based on patient data and medical knowledge. Predicting disease progression, treatment response, and potential adverse events by generating synthetic patient trajectories or simulating interventions.
6. **Medical Simulation and Training:** Generate synthetic anatomical models, surgical simulations, or virtual patient scenarios that healthcare professionals can use for practice, training, and improving their skills. This can enhance surgical planning, decision-making, and patient outcomes.



[AWS Machine Learning Blog](#)

## Announcing New Tools for Building with Generative AI on AWS

by Swami Sivasubramanian | on 13 APR 2023 | in [Amazon CodeWhisperer](#), [Amazon Machine Learning](#), [Artificial Intelligence](#), [Generative AI](#) | [Permalink](#) | [Comments](#) | [Share](#)

The seeds of a machine learning (ML) paradigm shift have existed for decades, but with the ready availability of scalable compute capacity, a massive proliferation of data, and the rapid advancement of ML technologies, customers across industries are transforming their businesses. Just recently, generative AI applications like ChatGPT have captured widespread attention and imagination. We are truly at an exciting inflection point in the widespread adoption of ML, and

## Microsoft and Epic expand strategic collaboration with integration of Azure OpenAI Service

April 17, 2023 | Microsoft News Center



**REDMOND, Wash., and VERONA, Wis. — April 17, 2023 —** Microsoft Corp. and Epic on Monday announced they are expanding their long-standing strategic collaboration to develop and integrate generative AI into healthcare by combining the scale and power of Azure OpenAI Service<sup>1</sup> with Epic's industry-leading electronic health record (EHR) software. The collaboration expands the long-standing partnership, which includes enabling organizations to run Epic environments on the Microsoft Azure cloud platform.

This co-innovation is focused on delivering a comprehensive array of generative AI-powered solutions integrated with Epic's EHR to increase productivity, enhance patient care and improve financial integrity of health systems globally. One of the initial solutions already underway, with UC San Diego Health, UW Health in Madison, Wisconsin, and Stanford Health Care among the first

## Extending Azure Health Bot with Azure OpenAI Service

Over the past few months, we have witnessed a tremendous shift in the way Artificial Intelligence (AI) is used across every industry. The adoption of Large Language Models (LLM) is gaining traction at an immense speed.

Azure Health Bot empowers healthcare organizations to build and deploy AI-powered, compliant, conversational healthcare experiences at scale. Already today, healthcare organizations are using Azure Health Bot to provide end users with self-serve functionality and easy to access information. The service combines built-in medical intelligence with natural language understanding tuned for clinical terminology in addition to easy customization and extension capabilities. But as with every chatbot, there are limitations to its ability to understand more complex questions or questions beyond its scope.

We are excited to share the preview of a new Azure Health Bot template that allows our customers to experiment with the integration of Azure OpenAI Service into their Health Bot instances for fallback answers. This feature does not aim to facilitate the bot to answer unknown queries in the medical space, rather, it enables

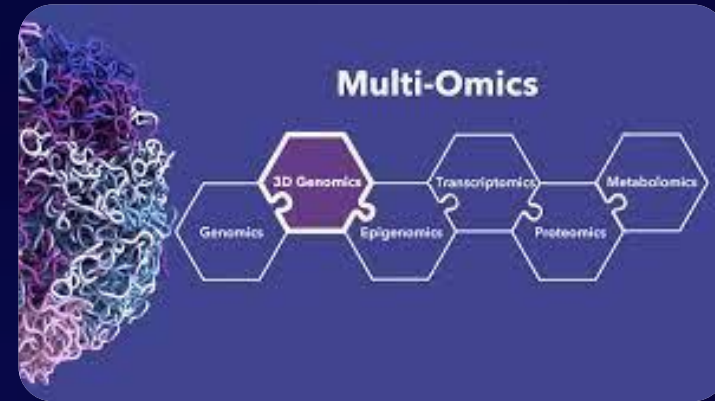
## Microsoft Alarmed By Doctors Using ChatGPT In Healthcare

enbrantaf - Newsenrthor Jun 16, 2023 | Updated Jun 16, 2023



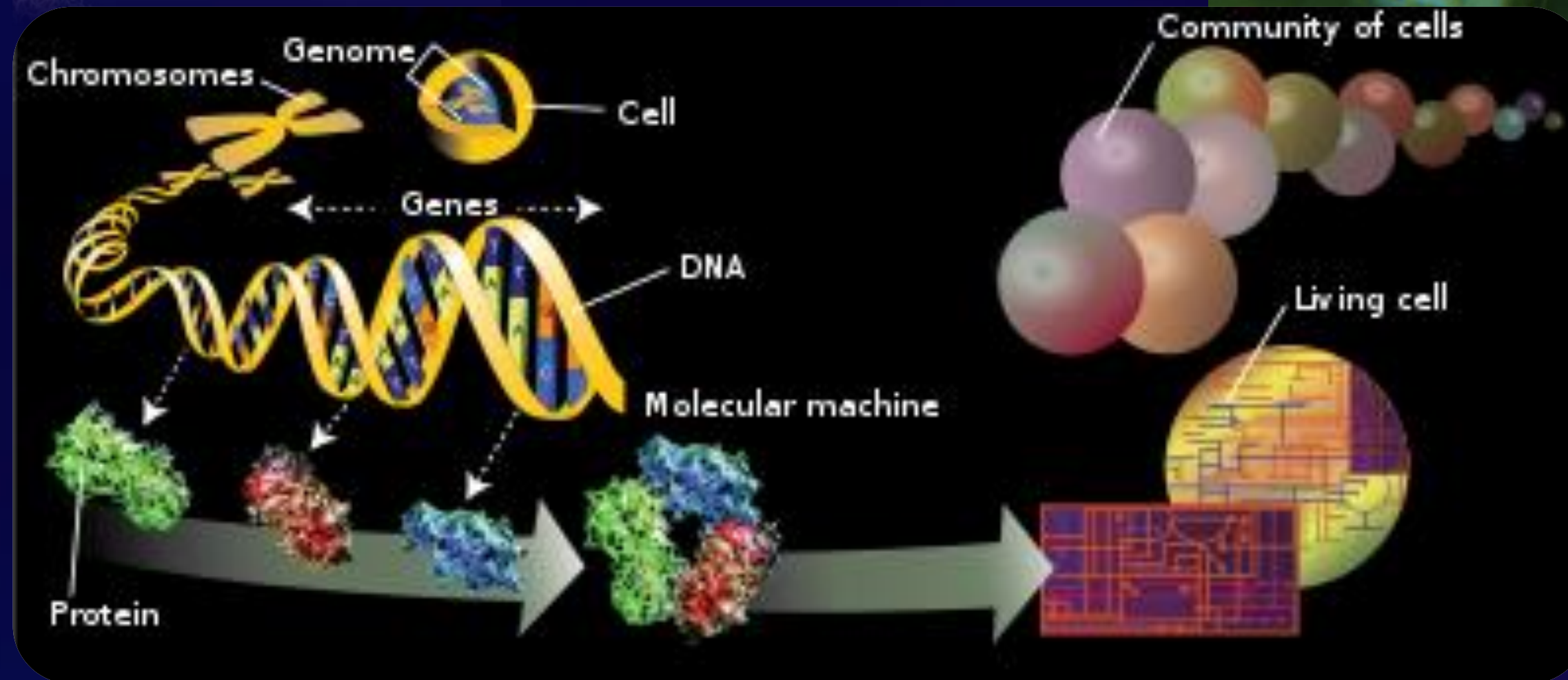
Doctors have begun using ChatGPT to help them talk to patients more empathetically. The tool also helps them explain medical information in simpler terms, without using confusing language. However, this innovative practice has raised concerns, even within Microsoft, which closely collaborates with OpenAI. Microsoft's own corporate vice president for research and incubations Peter Lee, told the NYT that he feels "weird" about it. The use of AI in healthcare continues to raise thought-provoking dilemmas, particularly in regards to ethics. This is particularly worrying as many doctors are beginning to make medical decisions through the use of AI.





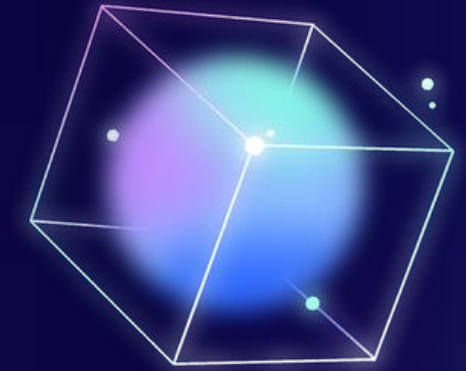
**“Getting the sequence was the easy part... The hard part is finding out what it means.”**

—Sydney Brenner, Genetic Biologist



**Genomics, Proteomics, Metabolomics, Metagenomics, Phenomics and Transcriptomics. Omics aims at the collective characterization and quantification of pools of biological molecules that translate into the structure, function, and dynamics of an organism or organisms**

# Regulation





# Machine Learning (ML)

## ML GAMP and Regulation (FDA and CE)

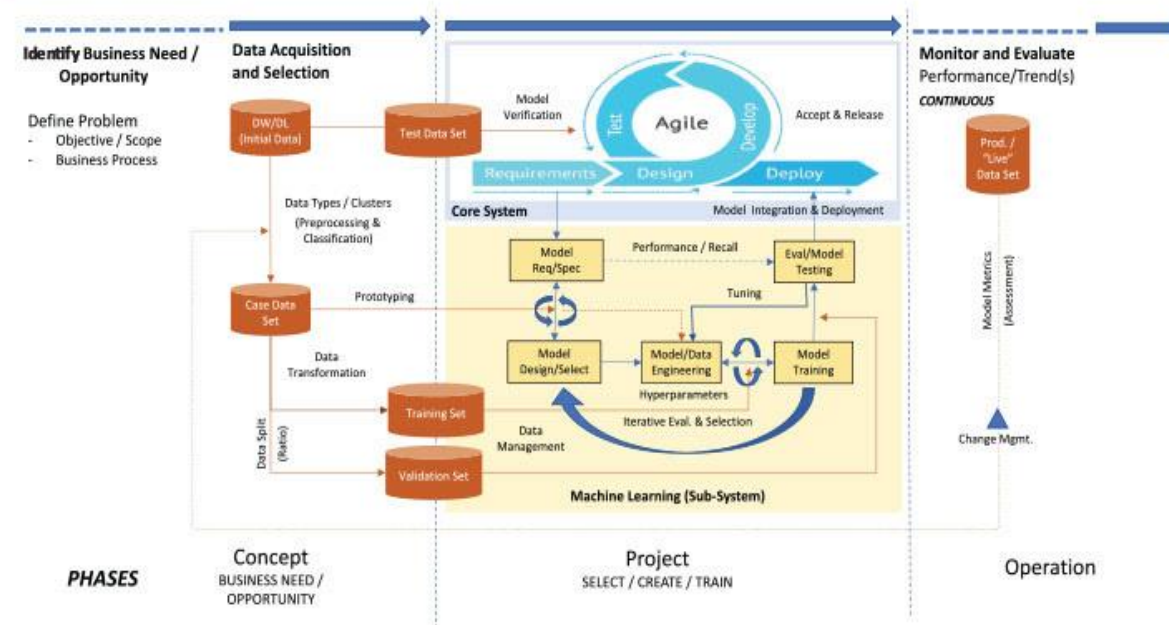
• AI / ML Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning -Enabled Device Software Functions

• AAMI 34971:2023 Application of ISO 14971 to machine learning in artificial intelligence. Guide

• US Food and Drug Administration. “Good Machine Learning Practice for Medical Device Development: Guiding Principles”.

• Applying GAMP® Concepts to Machine Learning

Figure 1: ML subsystem life cycle.



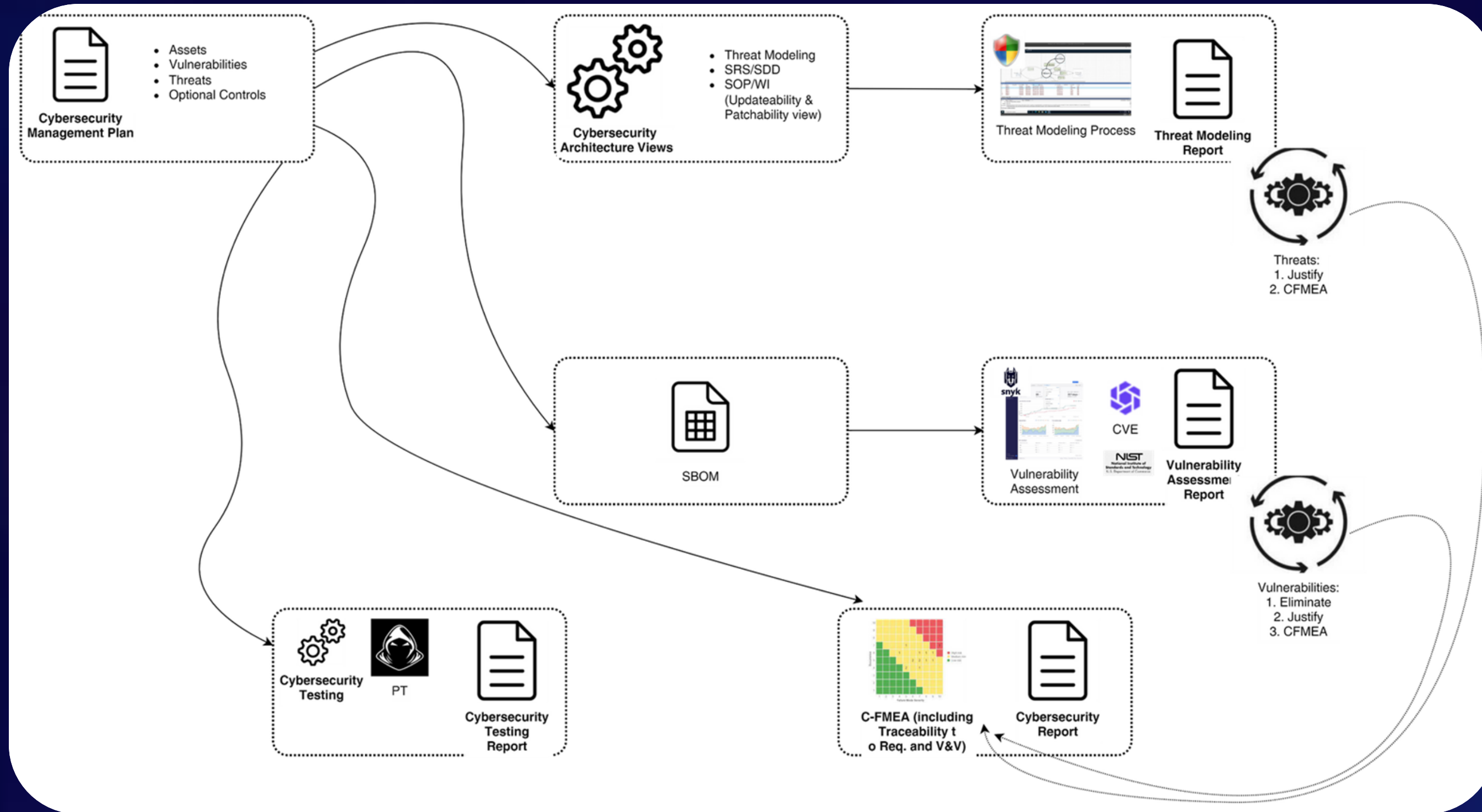
PHASES: Concept BUSINESS NEED / OPPORTUNITY, Project SELECT / CREATE / TRAIN, Operation

## Cybersecurity standards, FDA guidances

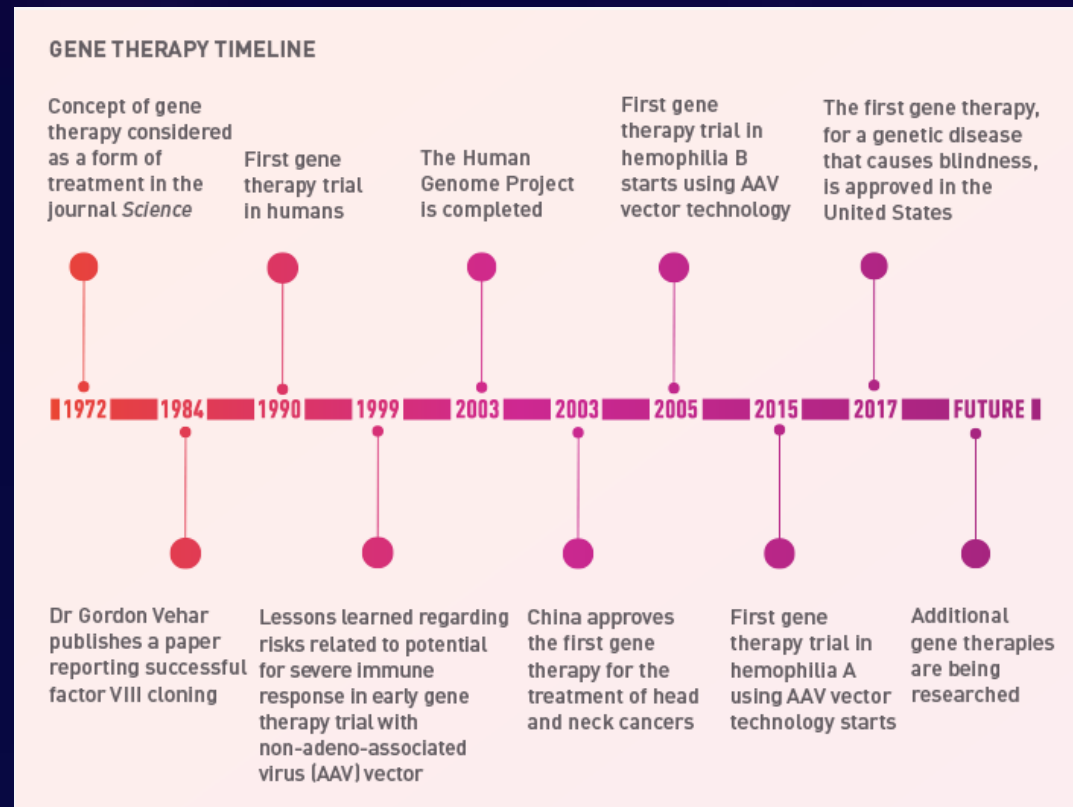
- **FDA Guidance: Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions**
- **FDA Guidance: Postmarket Management of Cybersecurity in Medical Devices**
- **FDA Guidance: Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software**
- **MDCG 2019-16 - Guidance on Cybersecurity for medical devices**
- **ANSI/AAMI TIR57:2016 – Principles for Medical device security – Risk Management will be employed**
- **NIST.SP.800-53r5**
- **ANSI/AAMI SW96:2023 Standard For Medical Device Security - Security Risk Management For Device Manufacturers**



# Cybersecurity Design and V&V in practice



- (Continuous) Machine Learning
- Genomics
- Omics
- Gen AI



FDA U.S. FOOD & DRUG ADMINISTRATION

← Home / Science & Research / Scientific Meetings, Conferences, and Workshops / FDA Omics Days 2023 - 10/10/2023

SYMPOSIUM | MIXED

## FDA Omics Days 2023

OCTOBER 10 - 11, 2023

FDA U.S. FOOD & DRUG ADMINISTRATION

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/ FDA Releases Two Discussion Papers to Spur Conversation about Artificial Intelligence and Machine Learning in Drug Development and Manufacturing

## FDA Releases Two Discussion Papers to Spur Conversation about Artificial Intelligence and Machine Learning in Drug Development and Manufacturing

## GenAI presents challenges to FDA medical device regulation, say experts

Despite advantages in medical imaging and improving access to mental health care, GenAI is still in the infancy stages of a regulatory framework.



# Thank you

Moshe

054-6695800

[moshe@medi-software.com](mailto:moshe@medi-software.com)



**MDI** EXPO  
2024