

Personalised Medicine 2030

How AI Transforms Care, Costs, and Competitiveness

Kristina Eskenazi · Chair, Health & Life Sciences Cluster Bulgaria

Biotechnology panel · Varna Hall · 05.10.2026

Nice to meet you!



LEADERSHIP

- Chair, Health & Life Sciences Cluster Bulgaria
- Chair, AI Cluster Bulgaria
- Vice President of the Board, CEBR – Council of European Bioregions
- Founder, Spinoff Europe
- Management Board, KRIB
- NCP Horizon Europe
- Member: EuropaBio, European AI Forum, ECHAlliance, Triple I, International Scientific Council of the Medical and Pharmaceutical Industry Development Agency under the Ministry of Health of the Republic of Uzbekistan.



Kristina Eskenazi

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Our Focus

Both clusters run hands-on programmes that turn research and curiosity into applied skills.



AI CLUSTER BULGARIA



AI PhD Bootcamp 2026

Intensive multidisciplinary training for PhD students & young scientists across AI, biomedicine, bioinformatics and cybersecurity — ending in a Demo Day of AI prototypes.



AI Girls & SemiGirls

Talent-development tracks inspiring girls and young women into AI/ML, data science, microelectronics and chip technologies.



AI & I Factory

With the Digital National Coalition: a hybrid hackathon + workshop format for students building AI start-up ideas (2 editions run so far).



HEALTH AND LIFE SCIENCES CLUSTER



360-Degree Lab Series

Interactive events linking personalised medicine, AI, data governance, cybersecurity and innovation financing — including a dedicated Technology Transfer edition.



PRECISEU PM School

Flagship personalised-medicine training, hosted in a different EU region each year — the 3rd edition ran in Sofia, June 2026.



InnoMedCatalyst Accelerator

Supports digital-health and diagnostics start-ups; awardees present at WMF, the Health Investor Summit and 4YFN.

EUROPEAN PROJECT PORTFOLIO



Interregional red biotech & pharma innovation



Smart Health Excellence Hub, SE Europe



Personalised medicine across Europe



Digital health & 5P medicine accelerator



Environmental effects on health



European Partnership on One Health Antimicrobial Resistance

European Partnership on One Health AMR



EDIH Trakia: cyber & digital maturity for SMEs

C3BG

Chips Centre of Competence Bulgaria

INNAXE

Aligned innovation agendas across the EU

12+

active EU-funded projects and initiatives

50+

clusters in 17 countries in CEBR, where Kristina Eskenazi is Vice President

3,500+

members of the European AI Forum, co-founded by AI Cluster Bulgaria

14,000

health stakeholders reached across Europe



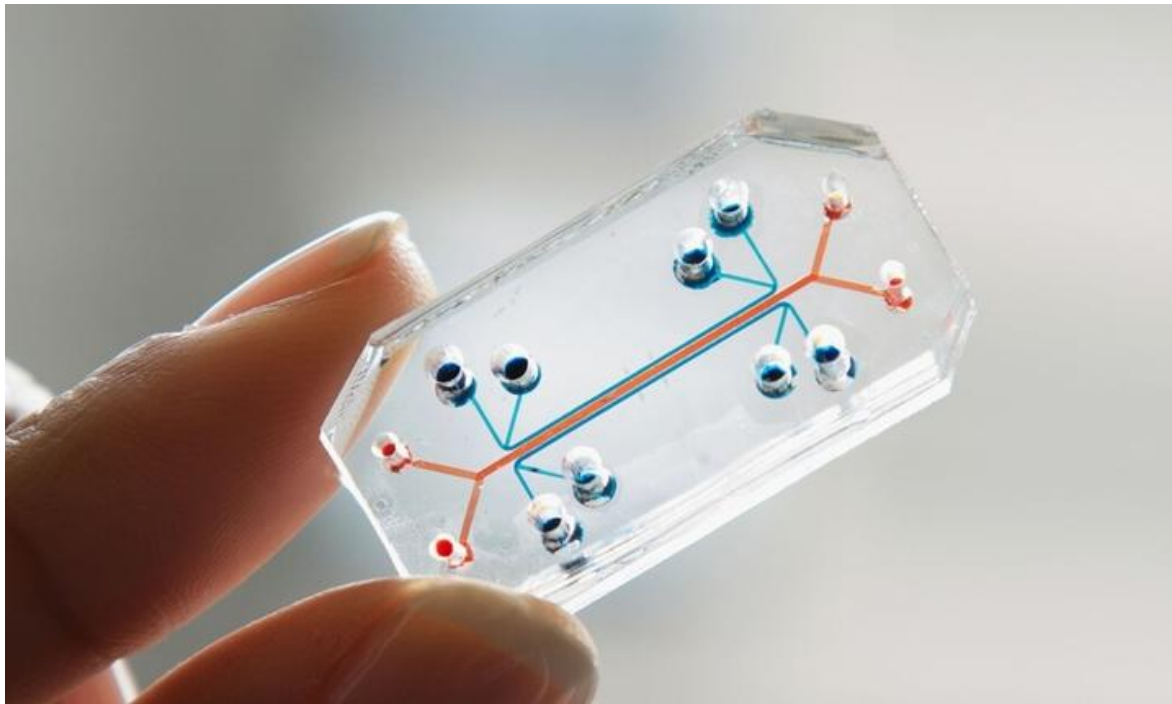


Personalised Medicine 2030

The future of health is loading...

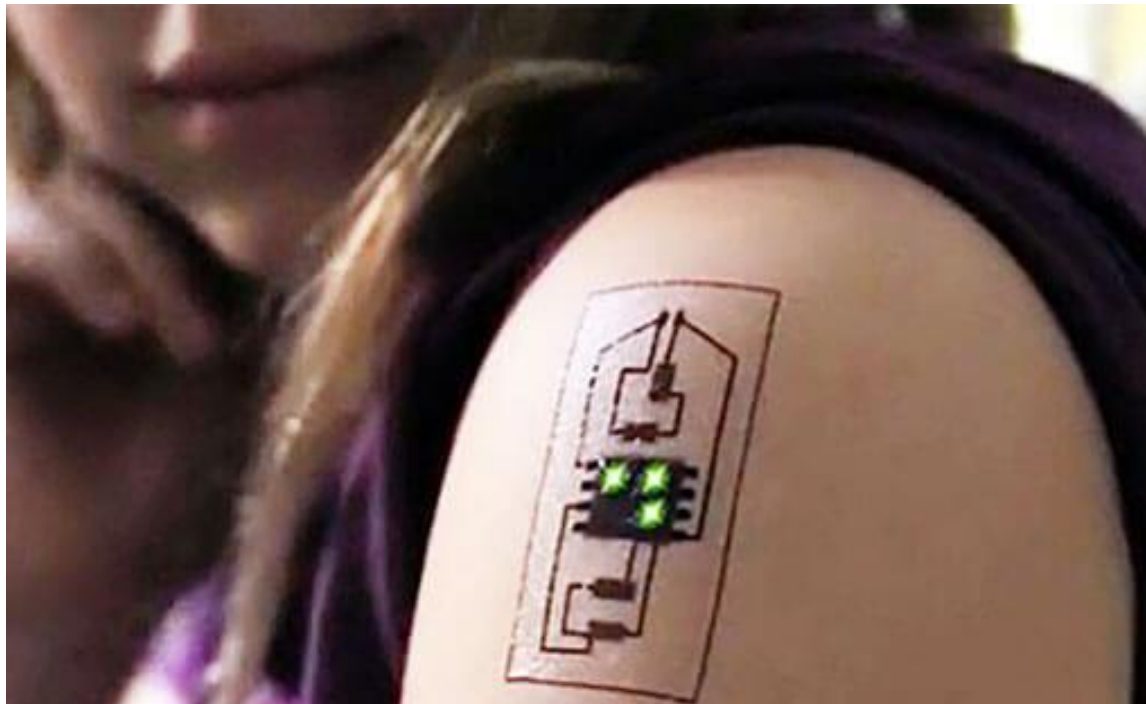
The Future of Health Is Now!

CONNEXUS

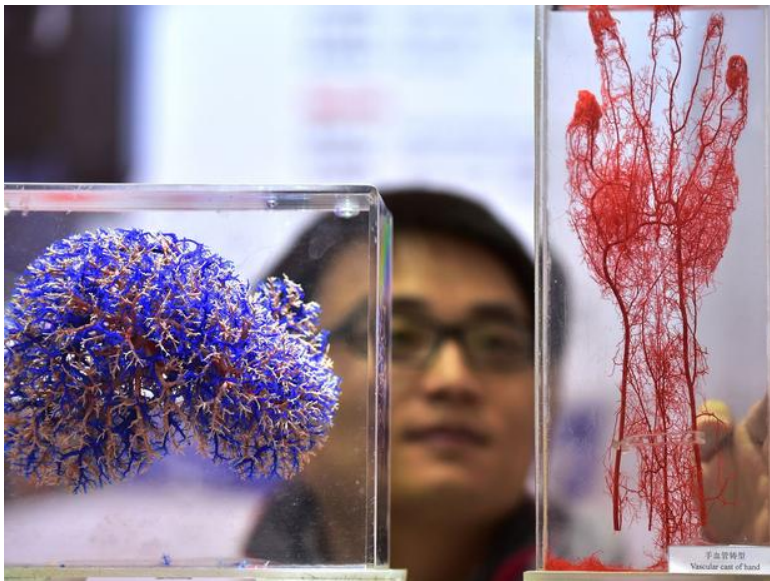


In silico clinical trials

The Organs-on-Chips technology is able to use stem cells to mimic organs of the body with a series of devices.



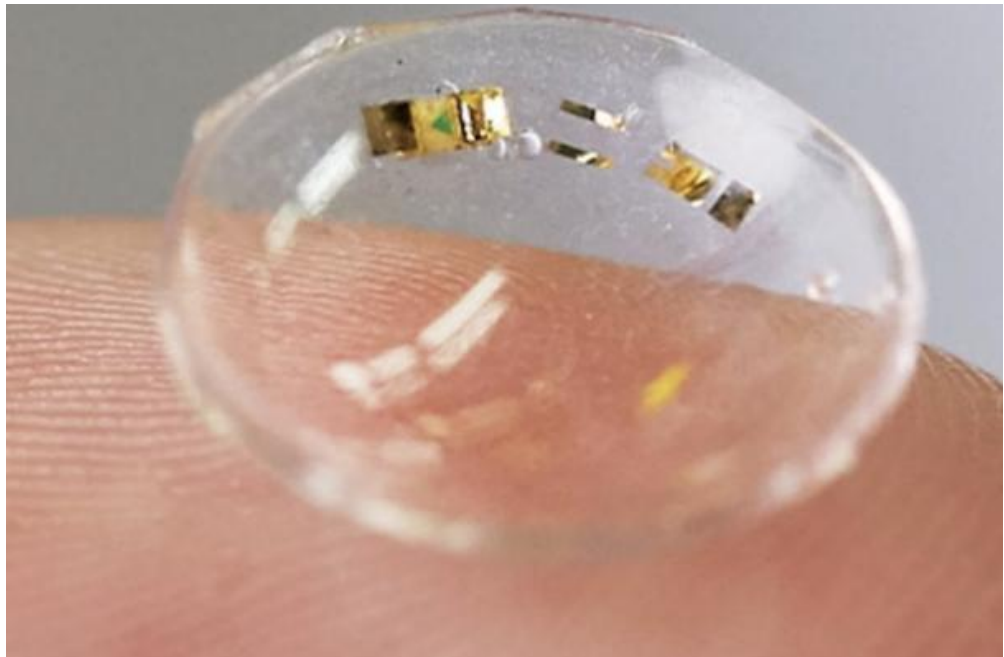
Biometric tattoos such as
VivaLNK's eSkin Tattoo



3D bioprinting human
tissue



Medical
tricorders



Keeping an Eye on Health
Contact lenses that track glucose levels from tears.



Avatar therapy in virtual reality.
Built for psychiatric care

Healthcare Trends



Evidence-based medicine

Research, guidelines and systematic reviews: safer, more consistent decisions.



Precision medicine

Genomics, biomarkers and molecular diagnostics match patient and therapy.



Personalised medicine

The person behind the diagnosis: goals, lifestyle, risk and social context.



Real-world evidence

Records, registries, devices and patient-reported outcomes show what works in practice.



Real-time insights

Wearables, remote monitoring and decision support flag risk earlier.



Prevention & prediction

From reacting to illness to predicting risk and closing care gaps.

From the average patient to the individual person, **and from treating illness to preventing it**

Adapted from SanteNet, "From Evidence to Personalized Care" (2026)

From concept to care

How it works together?



Evidence + individual context + real-world outcomes + live data + prevention = **safer, earlier, more personal care**

Healthcare Technology Trends

CONNEXUS



Chatbots & Virtual Assistants



Digital Twins in Healthcare



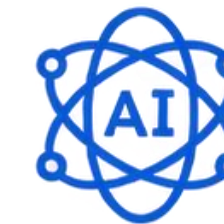
AI & Machine Learning



Telemedicine & Remote Monitoring



Robotics in Surgery & Assistance



Generative AI in Healthcare



Wearables in Healthcare



Blockchain in Healthcare Data



Predictive Analytics & Data Integration



Technology in Mental Health



Big Data Integration in Healthcare



Nanomedicine



Personalized Medicine & Genetic Testing



Internet of Medical Things (IoMT)



AR & VR in Healthcare



THE ENABLER

The background of the slide is a dark blue, stylized world map. It features glowing blue lines and dots that represent global connectivity, data flow, and network infrastructure. The map is centered on the Atlantic Ocean, with lines radiating outwards to various parts of the world, including North America, South America, Europe, Africa, and Asia. The overall aesthetic is futuristic and technological.

AI is the enabler.

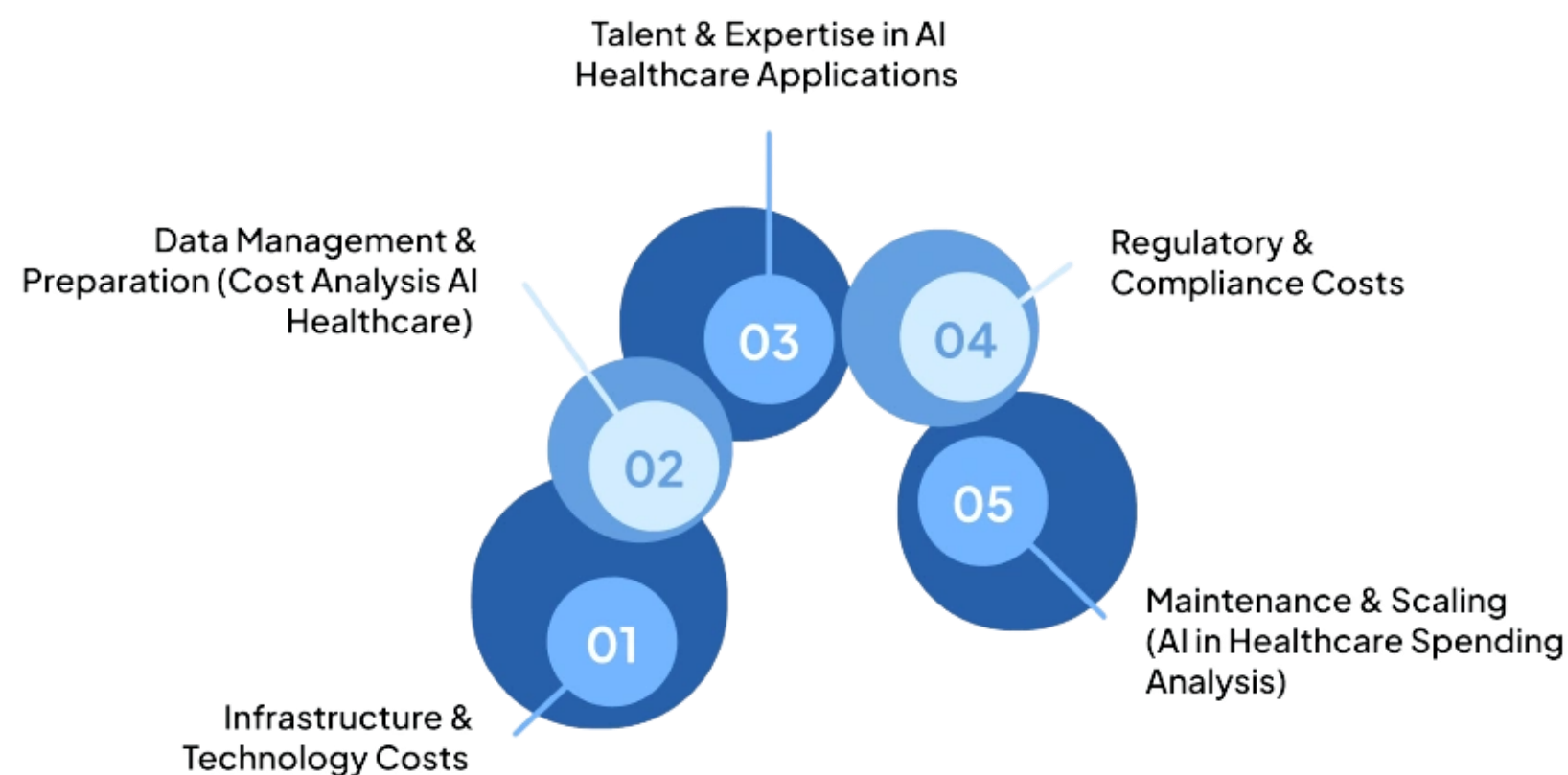
Data is the fuel.

Trust is the licence to operate.

WHAT WE BUDGET FOR?



The algorithm, the software, the compute



1

Infrastructure

Secure cloud & HPC, interoperability, cybersecurity

2

Data

Collection, curation, annotation and governance

3

Human capital

Data scientists, clinicians and regulatory experts as one team

4

Regulation

AI Act, MDR/IVDR, GDPR, EHDS, HTA

5

Clinical validation

Studies, evidence generation, post-market monitoring

The cost of AI in healthcare

Indicative implementation ranges in USD



Medical imaging AI

\$300k-\$900k



Hospital-wide integration

\$1m-\$5m



Patient-support chatbots

\$50k-\$200k



Predictive analytics

\$200k-\$600k

Beyond the budget: the economic, the social and the green price of AI — energy, e-waste and the trust we must earn.

ON THE HORIZON · REGULATIONS



LAYER · INSTRUMENTS

NEXT MILESTONES

1	Data GDPR · EHDS · Data Act · DGA	26 Mar 2027 EHDS applies	26 Mar 2029 EHDS secondary use opens	26 Mar 2031 Images, labs, discharge reports
2	AI AI Act	2 Aug 2026 · NOW Transparency duties (Art. 50)	2 Dec 2027 High-risk AI, Annex III	2 Aug 2028 AI in medical devices & IVDs
3	Health products MDR · IVDR · ATMP · SoHO	7 Aug 2027 SoHO Regulation applies	31 Dec 2027 IVDR class D transition ends	31 Dec 2028 IVDR class C transition ends
4	Evidence & access Clinical Trials Reg. · HTAR	Since Jan 2025 HTA: oncology & ATMPs	Jan 2028 HTA: orphan medicines	Jan 2030 HTA: all new medicines
5	Cybersecurity NIS2 · Cyber Resilience Act*	Ongoing NIS2 transposition	11 Sep 2026 CRA reporting duties	11 Dec 2027 CRA fully applies
6	Safety & liability Product Liability Dir. · Health Threats Reg.	Applicable Cross-border health threats	9 Dec 2026 Product Liability Directive transposed	
+	On the horizon Biotech Act · pharma package	16 Dec 2025 Biotech Act I proposed, in negotiation	2026 Biotech Act II (beyond health) expected	Expected 2028 EU pharma reform applies

Bold = the core three that decide whether a health AI product may exist. * CRA excludes products already covered by MDR/IVDR. Status at Oct 2026, after the AI Omnibus (Reg. (EU) 2026/1744).
Source: KEMNI, EUR-Lex.

ON THE HORIZON · BIOTECH ACT



WHAT BIOTECH ACT I BRINGS

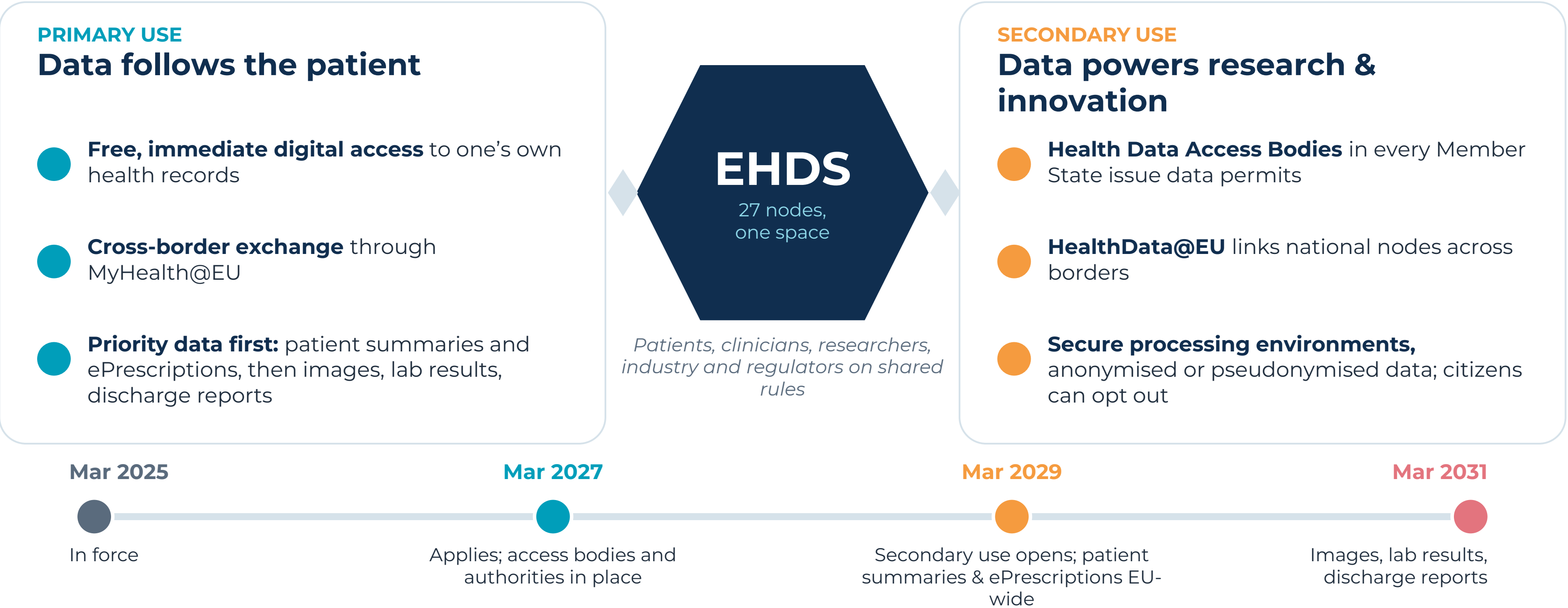
- 1 Strategic projects** priority status for high-impact health biotech
- 2 EU-EIB investment pilot** late-stage capital for the “valley of death”
- 3 Faster clinical trials** FAST EU, simpler multinational trials
- 4 Support network** help with rules, funding and scale-up
- 5 AI & data** built to use the European Health Data Space

WHERE IT STANDS · OCTOBER 2026



Not yet law: application expected from ~2028. EMA is already preparing CTIS, ~70% of which the proposal affects.
Sources: European Parliament, EMA, Council (Sept 2026).

Regulation (EU) 2025/327 · in force since 26 March 2025 · one framework, two uses of health data



For innovators: from 2029 a lawful, EU-wide route to data for training and validating AI.

VELES

Excellence Hub for Smart Healthcare

CONNEXUS

Building the first Regional Smart Health Data Space in South-East Europe

a stepping stone into the European Health Data Space

15

partners,
quadruple helix

7

countries: BG, RO,
GR, CY + SE, ES,
DE

2023–27

June 2023 – May
2027

WIDERA

Horizon Europe
Excellence Hub

VELES Polygon at GATE

A testing and simulation environment where teams prototype data-driven health services.

FOUR PILOTS ON ONE DATA SPACE



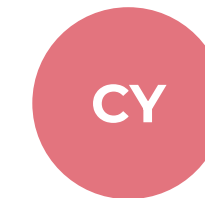
Alzheimer's disease
Bulgaria



Cancer treatment
Greece



Cerebral tumours
Romania



Dementia
Cyprus



The Smart Health Excellence Hub in SE Europe



Funded by
the European Union

Scan for newsletter
subscription!



Funding · EU opportunities



European Prize for Women Innovators 2027

EIC & EIT · Horizon Europe · prizes for women founders behind breakthrough innovations

Women Innovators

€100k · €70k · €50k

No age limit

Deadline: 1 Dec 2026, 17:00 CET

Rising Innovators

€50k · €30k · €20k

Under 35 (born on or after 1 Jan 1991)

EIT Women Leadership

€50k · €30k · €20k

Direct link to the EIT Community

Who: women founders or co-founders of a company registered in the EU or an associated country before 1 Jan 2025.

How: 15-page application + 90-second video. Scored on breakthrough innovation, impact and inspiration (min. 6/10 each).

Know a woman founder in health or biotech? Make sure she applies.

CLOSED 29 SEPT 2026

EU Award for Gender Equality Champions

4 × €100,000 for universities and research organisations with a Gender Equality Plan Sustainable · Newcomer · Inclusive. Results Jan–Mar 2027; an annual prize, so prepare for the next round.

FUNDING INSTRUMENTS

Horizon Europe · Health collaborative R&I consortia

Innovative Health Initiative public-private partnership with industry

EIC Pathfinder & Accelerator grants and equity for deep tech

EU4Health health systems and digital health

EP PerMed transnational calls in personalised medicine

Funding · EU opportunities



€3.2 bn

DIGITAL budget 2025–27

151

EDIHs, 136+ offering AI services

5

dedicated health call topics, 2025–27

WHAT IT BUILDS FOR HEALTH

- **Health data space** EHR exchange format, MyHealth@EU, EHDS readiness
- **Genomics** Genome of Europe & 1+MG data infrastructure
- **Cancer imaging** Cancer Image Europe platform for AI
- **AI testing & twins** TEF-Health, Virtual Human Twins
- **Cyber for hospitals** European Cybersecurity Support Centre

Bulgaria’s doors in: EDIHs incl. Cyber4All 2.0 EDIH Trakia · BRAIN++ AI Factory · VELES regional data space

HEALTH CALLS · WORK PROGRAMME 2025–2027

Topic	Budget	Deadline	Status
Genomic data infrastructure in the EHDS	€22.5 m	3 Mar 2026	CLOSED
Multi-modal AI in medical imaging (cancer)	€14.4 m	3 Mar 2026	CLOSED
AI-based image screening in medical centres	€9 m	1 Oct 2026	JUST CLOSED
EHDS capacity: EHR format & digital health services	€16 m*	1 Oct 2026	JUST CLOSED
Virtual Human Twins & AI in health incubator	€8 m*	2027	UPCOMING

Next window: the 2027 Virtual Human Twins call. From 2028, the Commission proposes folding DIGITAL and EU4Health into one European Competitiveness Fund.

* Indicative Work Programme budget. Status at 2 Oct 2026. Sources: Digital Europe WP 2025–2027 (C(2025) 1839), EU Funding & Tenders Portal, DG CNECT info days, EPRS.

Ecosystem opportunities



ABOUT THE INITIATIVE

Founded by AI Cluster Bulgaria and Health and Life Sciences Cluster Bulgaria, Spinoff Initiative connects Bulgaria's deep-tech, HealthTech and BioTech ecosystem to Europe's innovation landscape.



Spinoff Europa Conference

Annual flagship conference — talks, B2B matchmaking, 360-Degree Labs, Spinoff Showcases.



Health and Life Sciences Cross-Regional Hackathons

series of events, hosted under the Spinoff Initiative umbrella.



Spinoff of the Year

Annual award recognising Bulgaria's standout spinoff and deep-tech ventures.



Partnership Opportunities

Ways for companies, investors and institutions to plug into the ecosystem.

www.spinoff.bg/request-the-spinoff-report
www.spinoff.bg

CONNEXUS



SPINOFF REPORT 2026

Bulgaria's spinoff ecosystem and its role in Europe's innovation landscape — deep-tech, tech transfer, HealthTech, BioTech and AI.



Request at spinoff.bg

Request the Report



HLSC REPORT

PUBLISHING OCT 2026

Health and Life Sciences Cluster Bulgaria's annual look at the country's health & life-sciences ecosystem — biotech, medtech, digital health and cross-border collaboration.



Updates at biocluster.bg

Get Notified

Ecosystem opportunities

AI READINESS NAVIGATOR

Is your organisation AI-ready?

Author: Kristina Gaydarova, AMBA; AI Cluter Bulgaria

A practical tool that helps teams assess where they stand on AI and map out their next steps.



Start-ups & spinoffs

Check readiness before you scale or pitch.



SMEs & companies

See where AI can fit into your operations.



Research teams

Plan the path from lab results to AI-driven products.



TRY THE NAVIGATOR

Scan the code to open the AI Readiness Navigator on spinoff.bg.



spinoff.bg/ai-readiness-navigator

Ecosystem opportunities

CONNEXUS



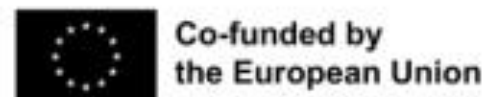
SME Access Call

Funding for imaging services
to advance your company's
innovation pipeline

Apply now!

*MRI images of a mouse brain,
acquired at the Euro-BioImaging,
Multi Modal Molecular Imaging
(MMMI) Italian Node.*

*Preclinical imaging with 7T MRI at the Center for
Advanced Preclinical Imaging (CAPI) at Charles University
in Prague. Image by Klara Stojanikova.*



Co-funded by
the European Union

eurobioimaging.eu



EMA support for innovators



SMEs · MICRO, SMALL & MEDIUM



Who is eligible

Micro <10 staff, ≤€2m · Small <50, ≤€10m · Medium <250, ≤€50m turnover or ≤€43m balance sheet.



Regulatory help & briefing meetings

Free 90-minute early dialogue on regulatory strategy; guidance on PRIME, scientific advice, CTIS, orphan & paediatric rules.



Fee incentives & translation

Reduced fees, deferred marketing-authorisation fee, and product info translated into all EU languages for free.



How to apply

Declaration form, annual accounts, ownership info and proof of establishment → sme@ema.europa.eu

ACADEMIA & NON-PROFIT DEVELOPERS



Fee incentives

Fee waivers and reductions available exclusively to academic and non-profit developers.



Guidance & advice

Written regulatory and scientific support, plus briefing meetings on development questions.



Regulatory science research

European Platform for regulatory science research, EMA's research needs and pre-competitive funded projects.



Communication

InfoDays, newsletters and targeted mailings designed for the academic community.

Talk to EMA early — it's free: SME@ema.europa.eu · +31 (0)88 781 8787 | academia@ema.europa.eu

TODAY'S PANEL



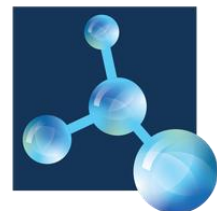
★	Dimitar Karlovski	Mitopia	Mitochondria as Qi: may the Force be with you
1	Prof. Elitsa Encheva	MU–Varna	Imaging tumours like never before
2	Prof. Anton Tonchev	MU–Varna	Zoom into the micro-world, and beyond
3	Prof. Kristina Bliznakova	MU–Varna	Early screening for breast cancer
4	Prof. Ruzha Pancheva	MU–Varna	AI for child nutrition: from data to personalised advice
5	Petyo Boshnakov	Chateau Boshnakov	Innovative technologies in winemaking
6	Assoc. Prof. Oskan Tasinov	MU–Varna	WineX: more than wine

★ Practical use case · 1–6 Innovation showcase, 8 min each, followed by moderated discussion

Thank you

Let's turn research excellence into scalable innovation,
together.

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www.biocluster.bg · www.aicluster.bg · www.spinoff.bg



HEALTH & LIFE SCIENCES
CLUSTER

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Spin**ff**
INITIATIVE