AI-ENABLED MEDICAL DEVICES

Progress • Potential • Challenges

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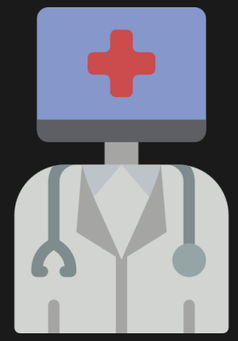
Use cases for artificial intelligence in healthcare



USE CASES FOR ARTIFICIAL INTELLIGENCE IN HEALTHCARE

CLINICAL DECISION SUPPORT

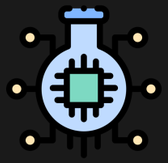
- Assisting clinicians in making decisions
- Using algorithms to analyze medical data
- Providing evidence-based treatment options, or alerts

ADMINISTRATIVE TASKS

- Appointment scheduling
- Processing patient information
- Supply chain management

TRAINING AND EDUCATION

- Automated feedback systems
- Simulation of medical conditions

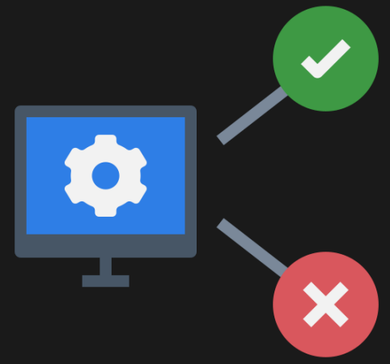


RESEARCH

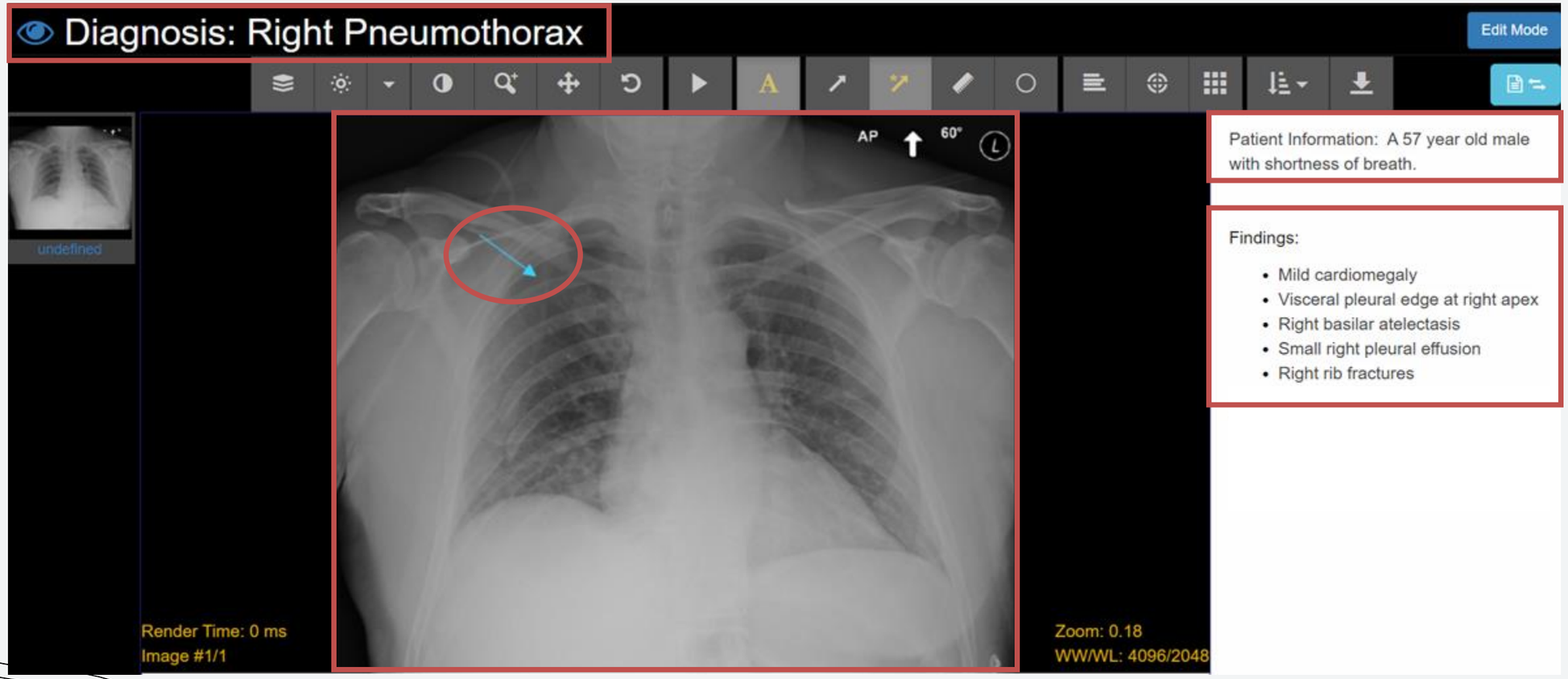
- New drug discovery
- New technologies and technological features
- Gentic profiles

ARTIFICIAL INTELLIGENCE IN THE HEALTHCARE CONTEXT: PERCEIVED RISK

AI-enabled clinical decision support in different medical fields



AI in radiology



Source: OWN

AI in cardiology

Zio XT

Zio XT Final Report for

Report, Patient #16 1

iRhythm Technologies
Tel: (888) 693-2401
www.zioreports.com

iRhythm

Date of Birth	Patient ID	Gender	Primary Indication (R94.31)
12/12/67 (51 yrs)		Female	Abnormal electrocardiogram

Prescribing Clinician	Managing Location
Dr. E. Physician	San Francisco

Enrollment Period	Analysis Time
13 days 19 hours 03/22/19, 05:24am to 04/05/19, 12:40am	13 days 19 hours (after artifact removed)

Ventricular Tachycardia (4 beats or more) 2

Episodes 5
HR Range 116-150 bpm
Avg 132 bpm

▼ Fastest VT (HR Range 135-150 bpm, Avg 142 bpm)

Pauses (3 secs or longer)

Episodes 3
Range 3.9-4.9 s

▼ Longest Pause (4.9 s, 12 bpm)

Atrial Fibrillation

AF Burden 37%
Longest Duration 1 d 19 h
HR Range 50-154 bpm
Avg 97 bpm

▼ Fastest AF (HR Range 61-154 bpm, Avg 100 bpm)

AV Block (2nd° Mobitz II, 3rd°)

None found

Supraventricular Tachycardia (4 beats or m

Heart Rate

Overall	Max	154 bpm	09:49am, 03/25
	Min	50 bpm	11:59pm, 03/22
	Avg	78 bpm	
Sinus	Max	96 bpm	11:14am, 03/24
	Min	50 bpm	11:59pm, 03/22
	Avg	66 bpm	

Patient Events

Total Triggers: 2 **Total Diaries: 1**

Findings within ± 45 sec of triggered events or diary entries:

	Range	Trigger	Diary
AF	59-126 bpm	✓	✓
Pause(s)	3.9 s	✓	
Sinus	56-73 bpm	✓	
SVE(s)		✓	
VE(s)			✓

3

Ectopics Rare Occasional Frequent

Preliminary Findings 4

Patient had a min HR of 50 bpm, max HR of 154 bpm, and avg HR of 78 bpm. Predominant underlying rhythm was Sinus Rhythm. 5 Ventricular Tachycardia runs occurred, the run with the fastest interval lasting 4 beats with a max rate of 150 bpm, the longest lasting 4 beats with an avg rate of 127 bpm. Episodes of Ventricular Tachycardia may be possible Atrial Fibrillation with aberrancy. Atrial Fibrillation occurred (37% burden), ranging from 50-154 bpm (avg of 97 bpm), the longest lasting 1 day 19 hours with an avg rate of 97 bpm. 3 Pauses occurred, the longest lasting 4.9 secs (12 bpm). Atrial Fibrillation and Pause were detected within +/- 45 seconds of symptomatic patient event(s). Isolated SVEs were rare (<1.0%, 6723), SVE Couplets were rare (<1.0%, 141), and SVE Triplets were rare (<1.0%, 9). Isolated VEs were rare (<1.0%, 1716), VE Couplets were rare (<1.0%, 192), and VE Triplets were rare (<1.0%, 26).

Final Interpretation

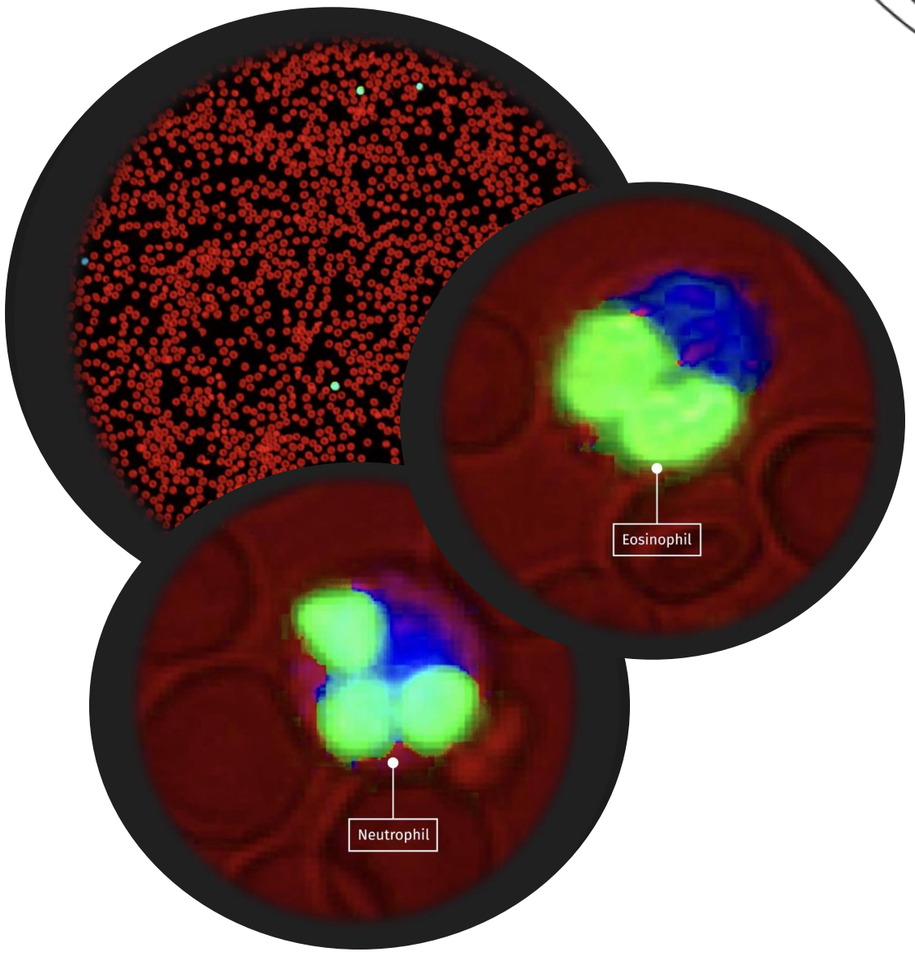
1. Agree with above interpretation
2. Underlying Sinus rhythm with normal rates average =78/min
3. 5 runs of VT some of which could be AF with aberrancy
4. Atrial fibrillation with 37% burden and longest run of 42 hours
5. Pauses of up to 4.9 seconds likely post conversion related
6. Triggered events consistent with AF, Pauses

Electronically signed by Dr. Example Physician 04/12/19 06:18 PM (CT)

SIGNATURE

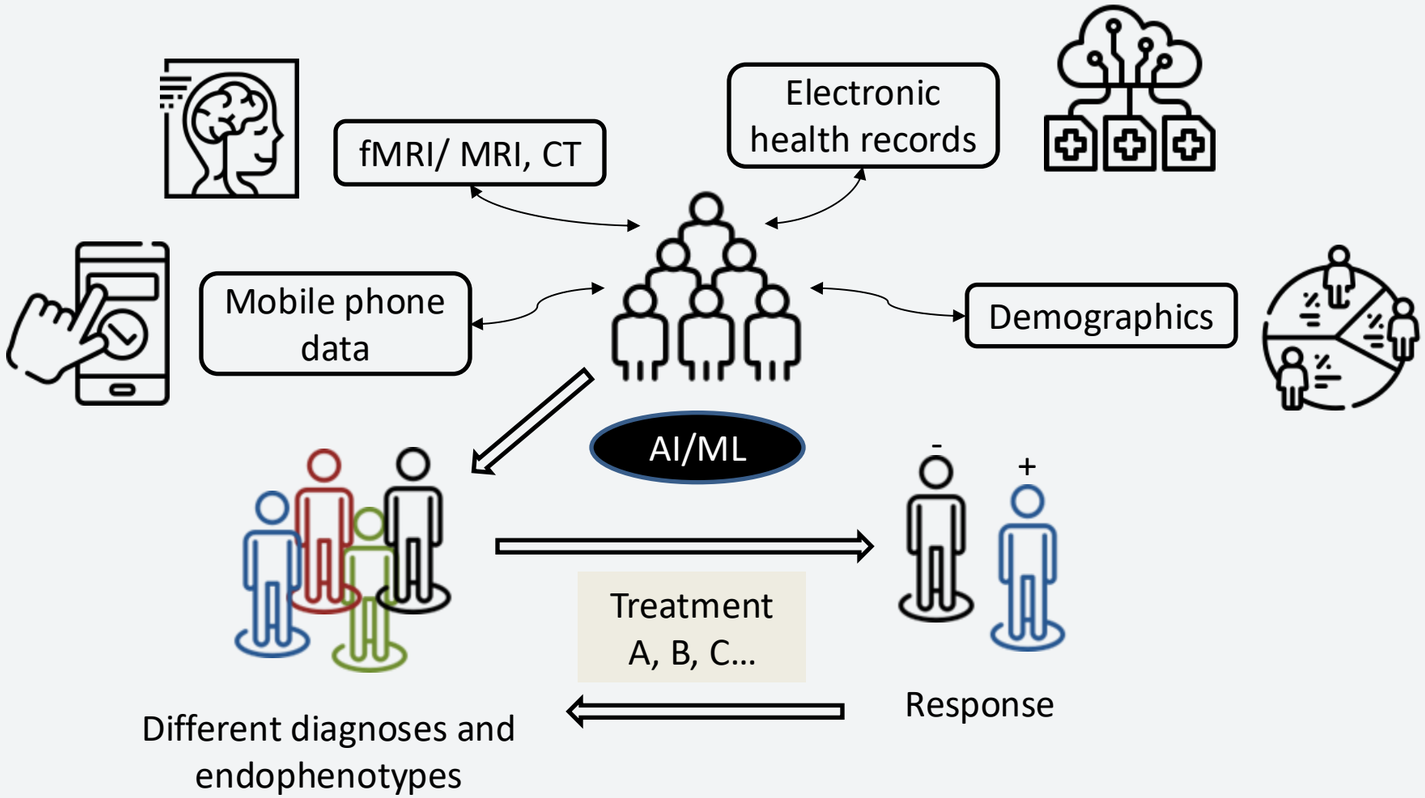
Source: Zio by iRhythm, https://www.irhythmtech.com/providers/zio-service/reporting

AI in hematology

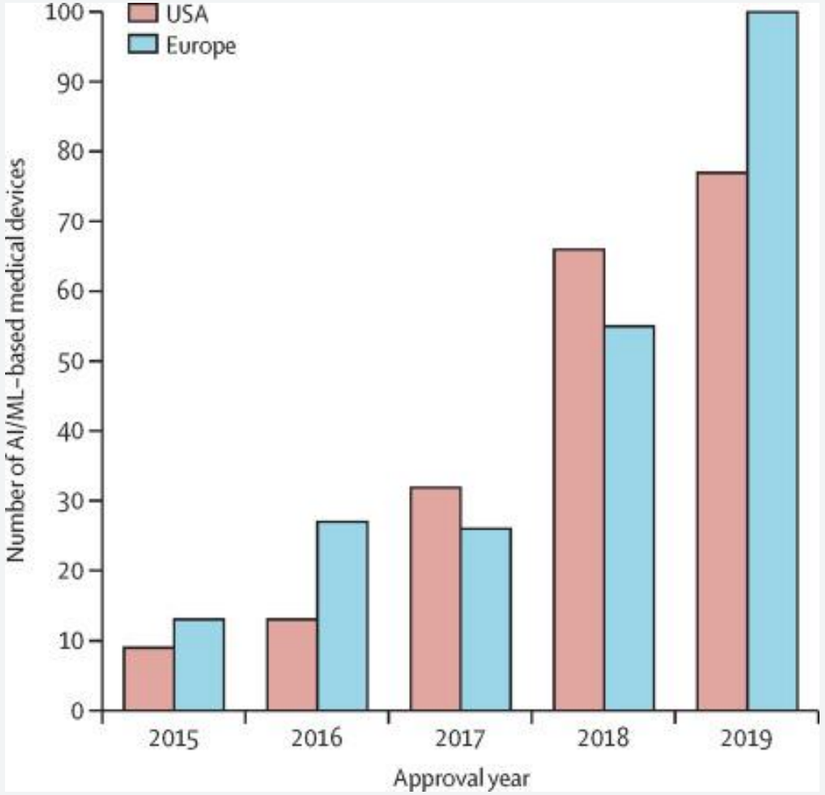


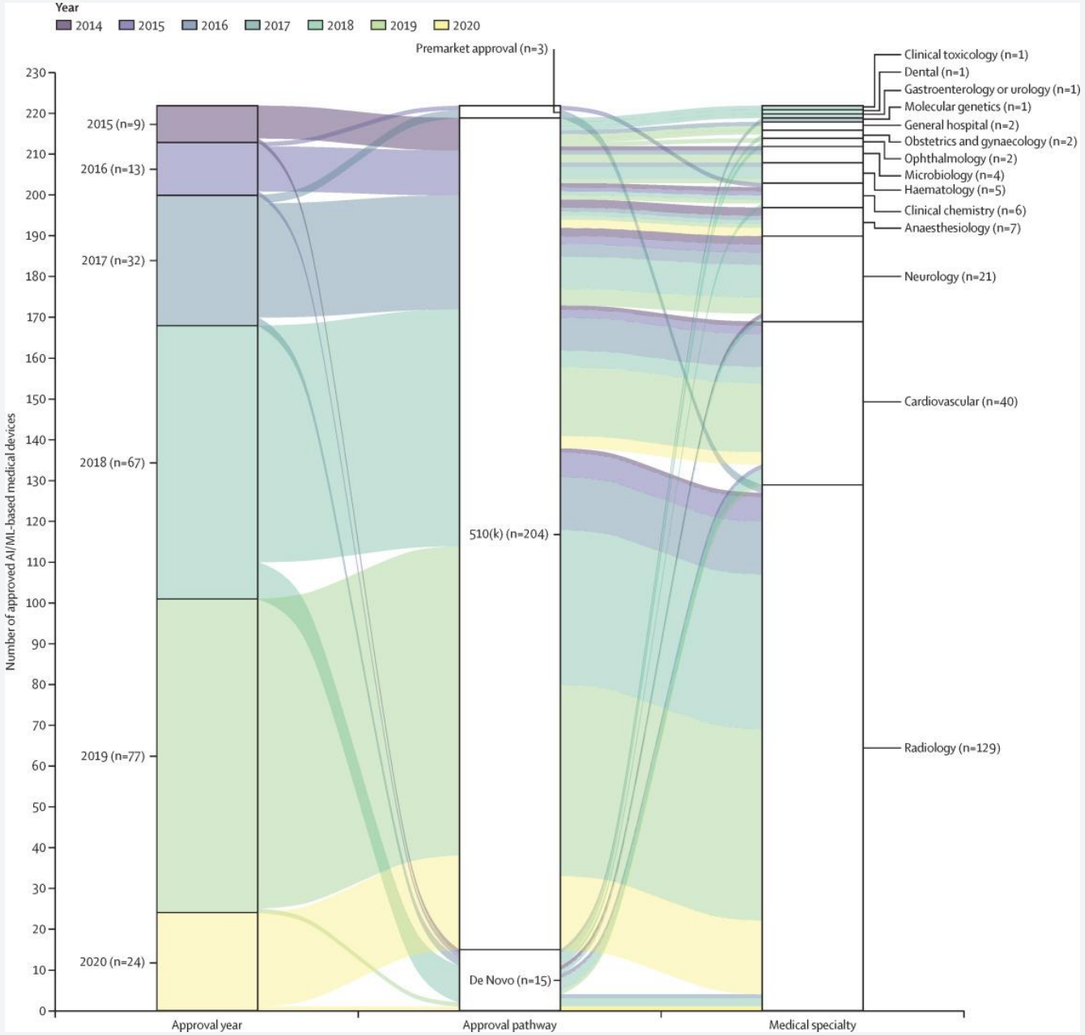
Source: Sight OLO, https://sightdx.com/en/product

AI in mental health: Dreams of the future



Regulated AI-CDSS in different medical fields





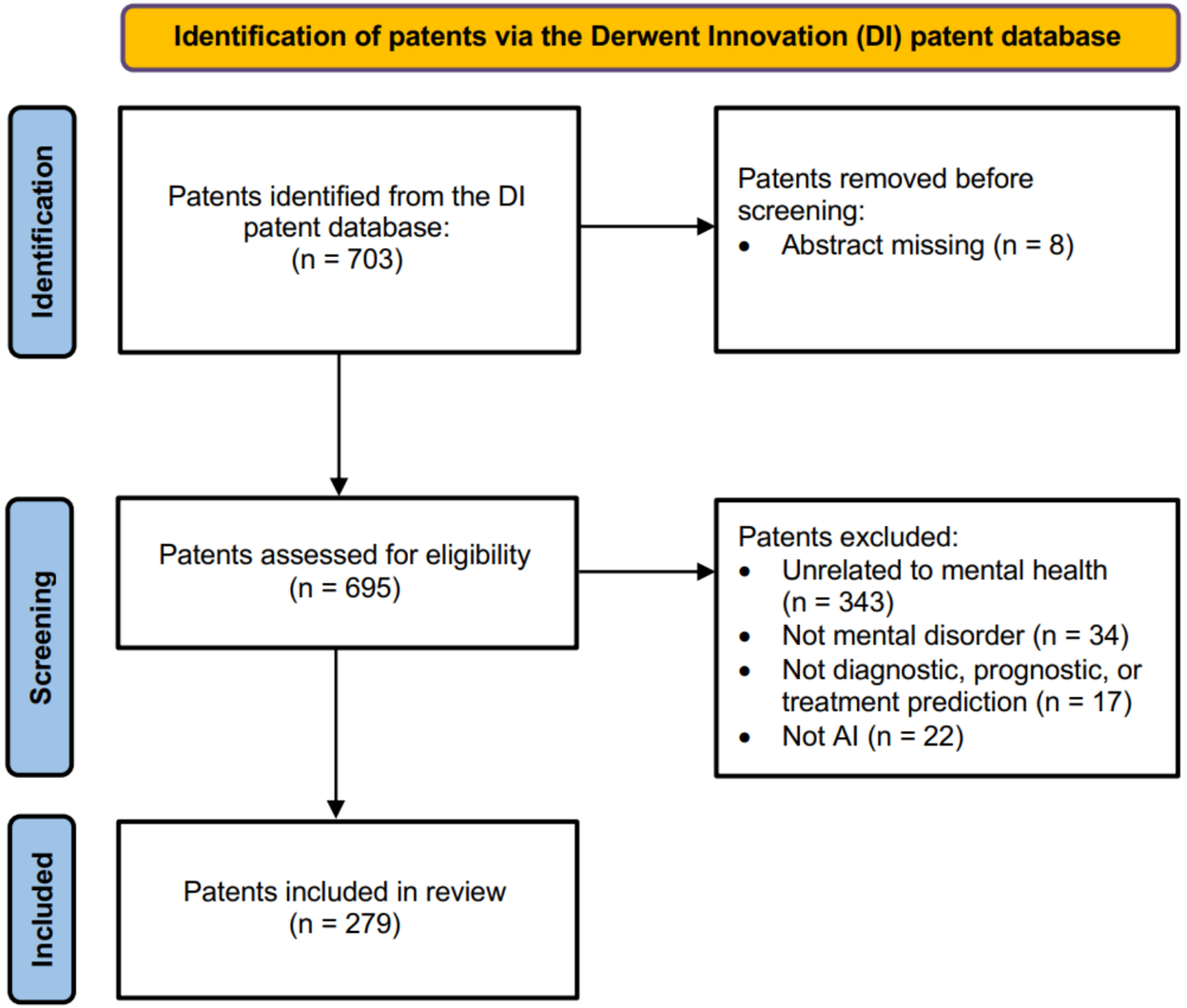
Source: Muehlematter et al. (2021). Approval of artificial intelligence and machine learning-based medical devices in the USA and Europe (2015–20): a comparative analysis.

Advancing Mental Health Care with AI-Enabled Precision Psychiatry Tools: A Patent Review

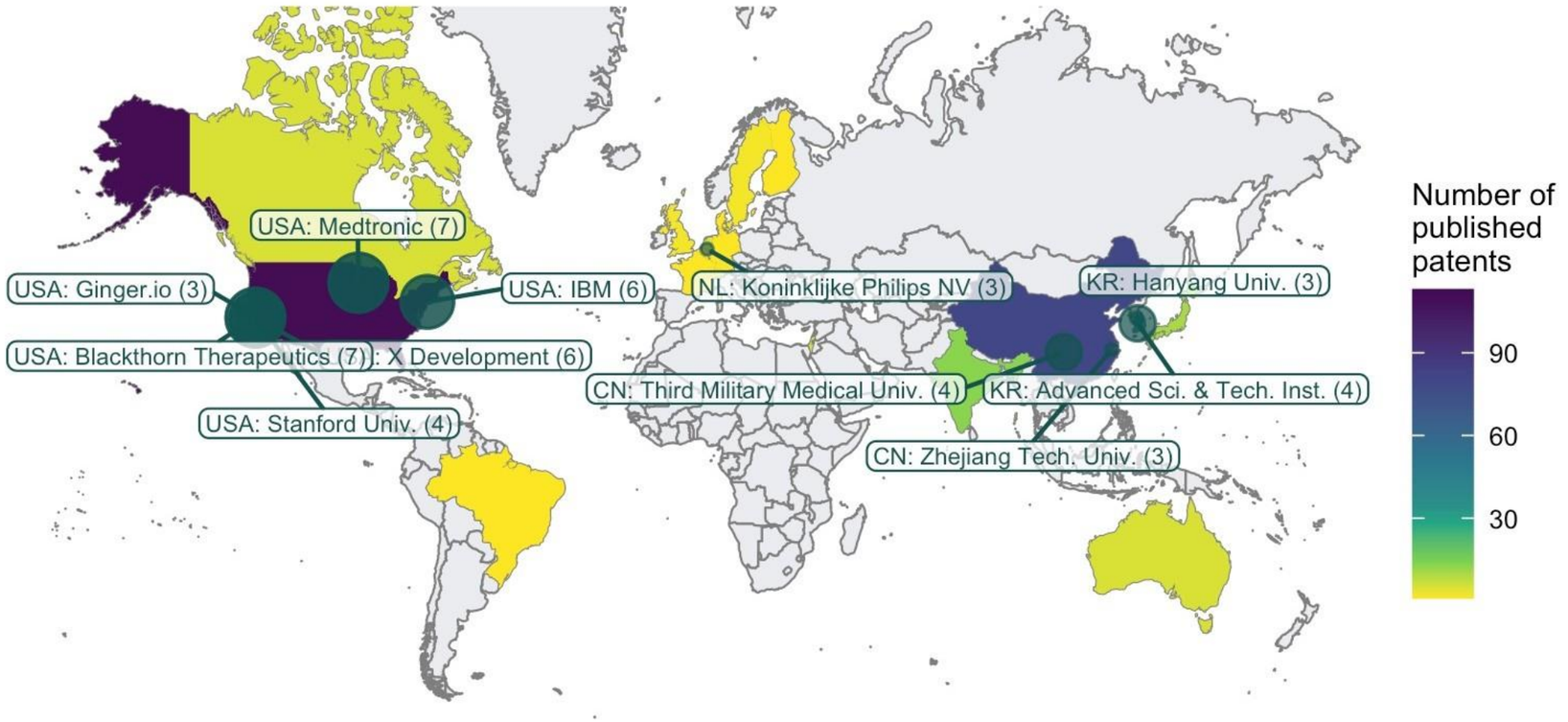
Derwent Innovation Patent Database

Diagnostic, treatment prediction, prognostic AI-enabled mental health tools

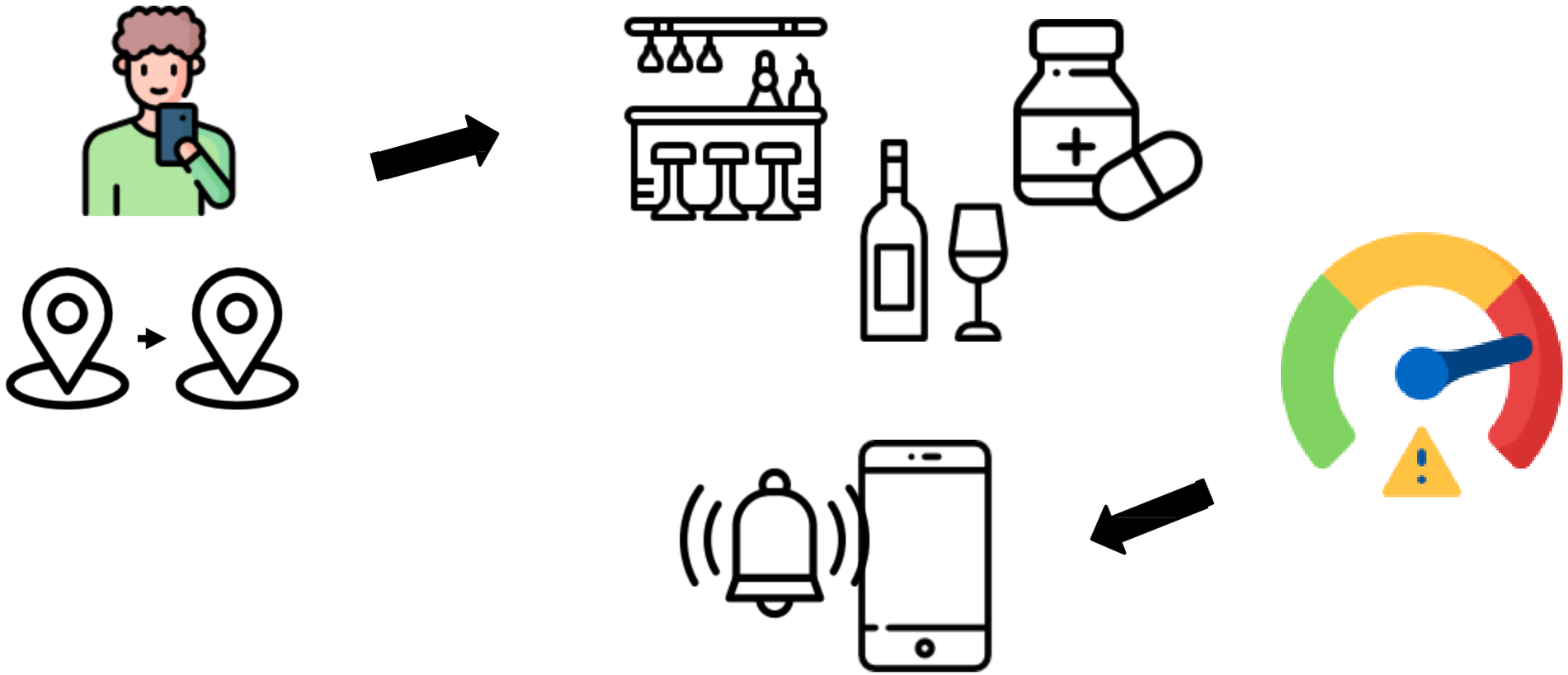
279 patents


Identification of patents via the Derwent Innovation (DI) patent database
Identification
Patents identified from the DI patent database: (n = 703)
Patents removed before screening:
• Abstract missing (n = 8)
Screening
Patents assessed for eligibility (n = 695)
Patents excluded:
• Unrelated to mental health (n = 343)
• Not mental disorder (n = 34)
• Not diagnostic, prognostic, or treatment prediction (n = 17)
• Not AI (n = 22)
Included
Patents included in review (n = 279)

Regional distribution

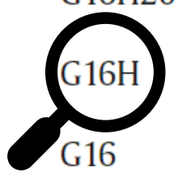


“Systems and methods of usingwireless location, context, and/ or one or more communication networks for monitoring for, preempting, and/or mitigating pre-identified behavior” (Williams et al., 2019)



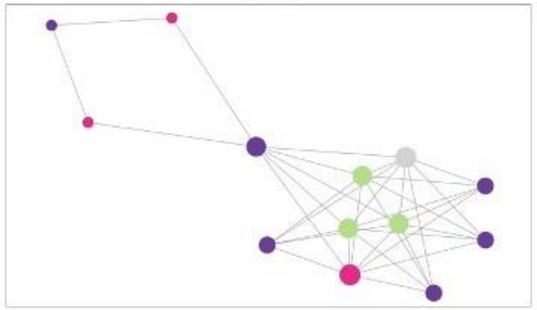
CPC Codes

CPC Code	Level	Explanation
G16H2070	Subgroup	Information and communication technology (ICT) used for steering or monitoring psychotherapy
G16H20	Group	ICT adapted for therapies or health-improving plans
G16H	Subclass	Healthcare informatics
G16	Class	ICT adapted for specific application fields
G	Section	Physics

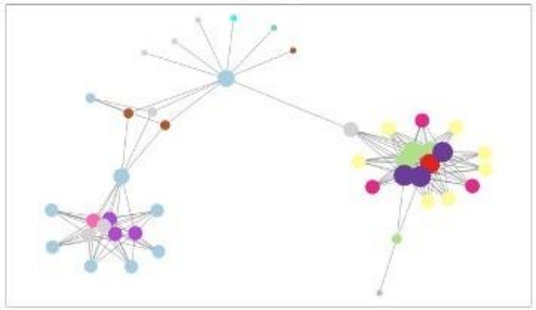


Technology convergence based on CPC codes

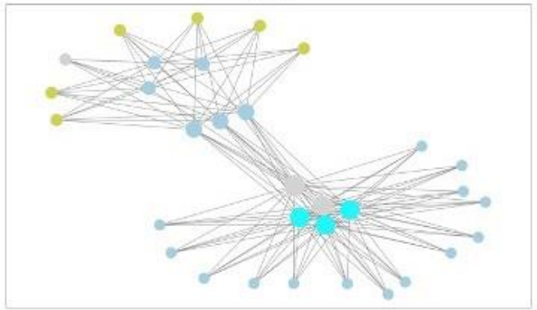
a) 2015



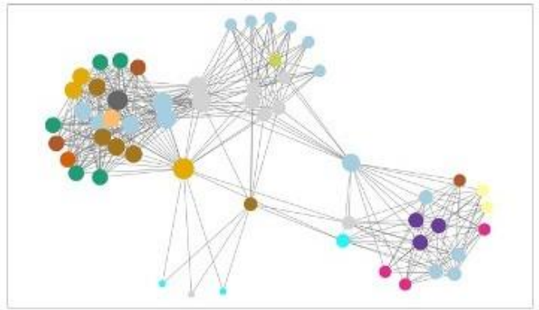
b) 2016



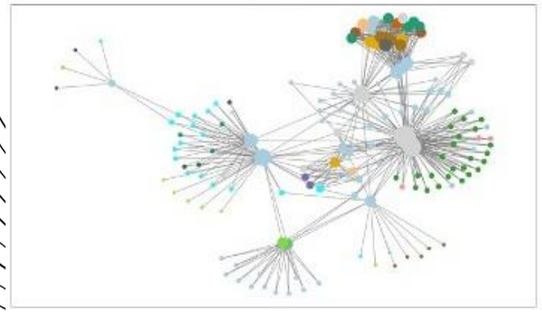
c) 2017



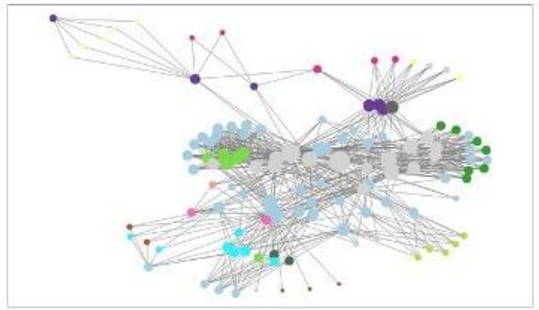
d) 2018



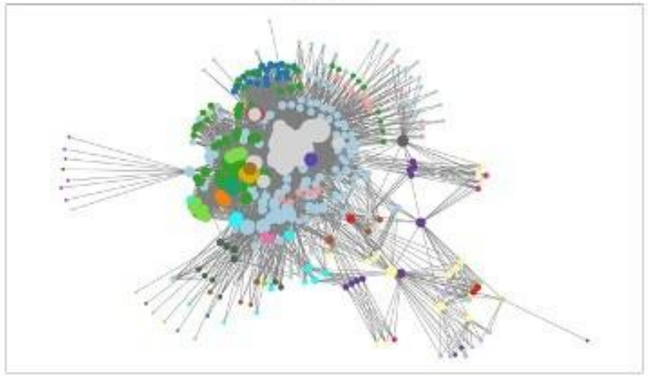
e) 2019



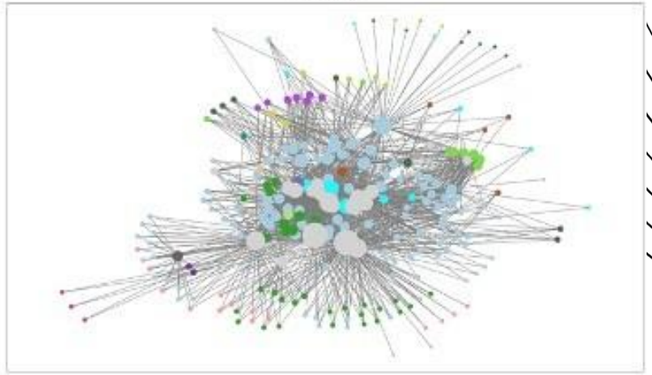
f) 2020



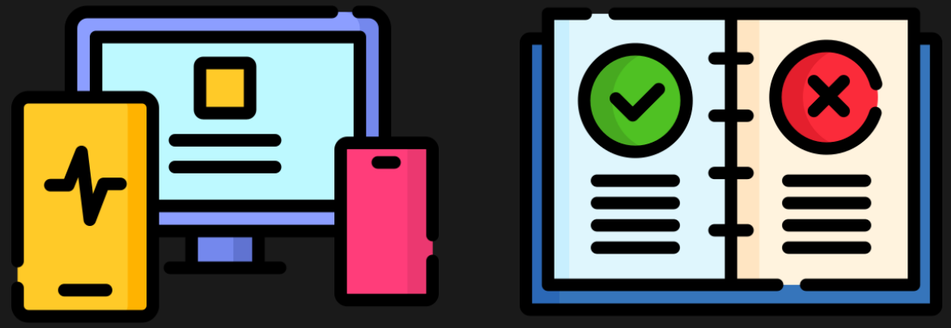
g) 2021



h) 2022

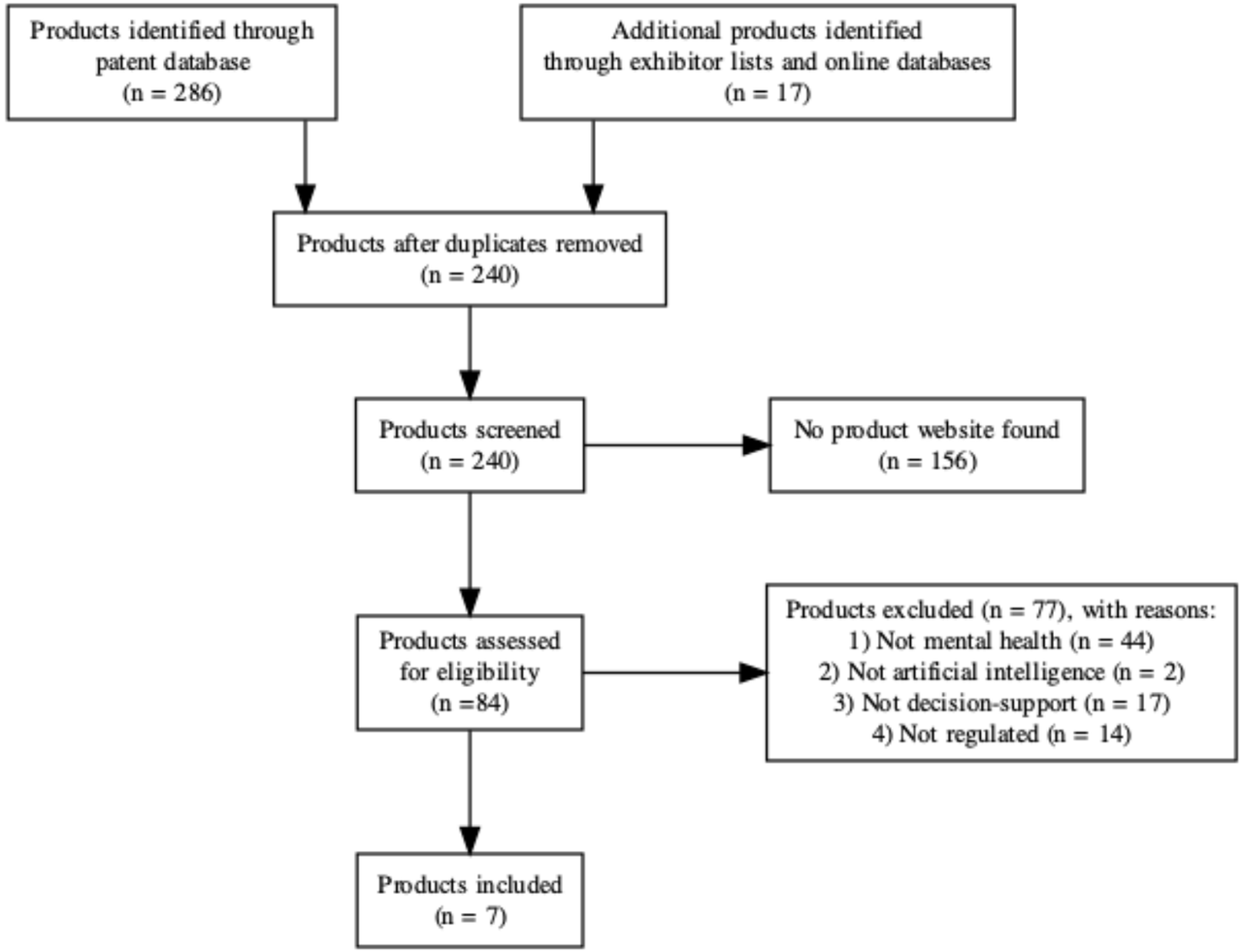


- (A61B) Diagnostic instruments and processes
- (A63F) Gaming
- (G01R) Measuring electric variables
- (G06Q) Data processing systems or methods for administrative purposes
- (G16B) Bioinformatics
- (A61H) Physical therapy apparatus
- (B25J) Manipulators
- (G01V) Geophysics
- (G06T) Image data processing or generation
- (G16H) Healthcare informatics
- (A61K) Preparations for pharmaceutical products
- (C12N) Microorganisms or enzymes
- (G05B) Control or regulating systems in general
- (G06V) Image or video recognition or understanding
- (G16Z) ICT for specific applications
- (A61M) Devices for introducing media into or onto the body
- (C12Q) Measuring or testing processes involving enzymes, nucleic acids, or microorganisms
- (G06F) Electronic digital data processing
- (G07F) Coin sorting
- (H04L) Transmission of digital information
- (A61N) Electrotherapy
- (G01N) Investigating or analyzing materials by determining their physical or chemical properties
- (G06K) Graphical data reading
- (G09B) Educational or demonstration appliances
- (H04W) Wireless communication networks
- (A61P) Therapeutic activity of chemical compounds or medicinial preparations
- (G01P) Measuring linear or angular speed, acceleration, or shock
- (G06N) Computing arrangements based on computational models
- (G10L) Speech analysis or synthesis
- (Y02A) Technologies for adaptation to climate change



A Review of Regulated AI Software Medical Devices for Mental Healthcare

Search results

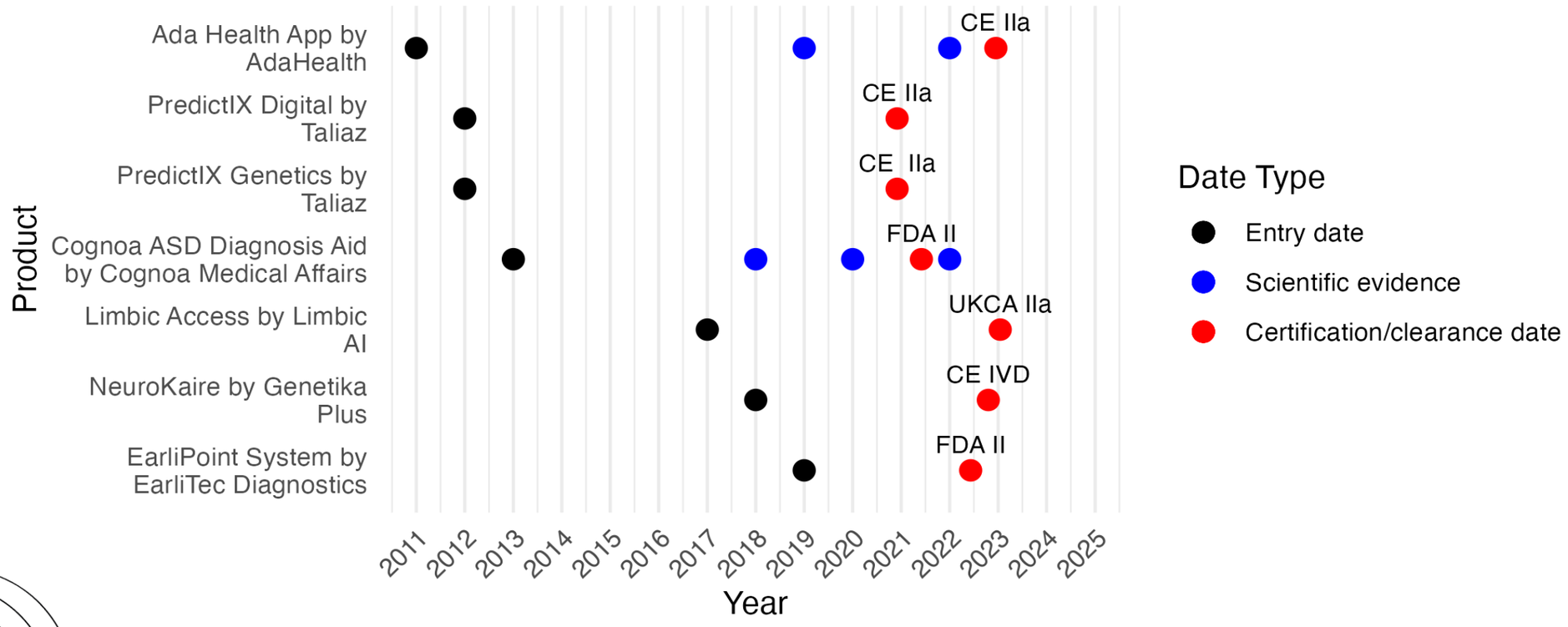


The identified products

[Example FDA regulation EarliTec]

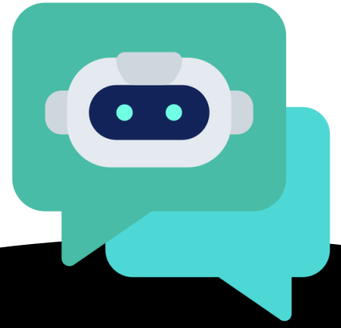
A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q
Product name	Company name	Certification	Predicate device	FDA_type	FDA_reg_number	Firm_Entry_date	Certification_date	Disorder	Input	Output	Characteristics	main_purpose	Price	Evidence_date1	Evidence_date2	Evidence_date3
Cognoa ASD Diagnosis Aid	Cognoa Medical Affairs	FDA II	NA	De_novo	DEN200069	2013	02.06.2021	Autism	Demographic, Questionnaire, Video	ASD diagnosis	The Cognoa ASD Diagnosis Aid is intended for use by healthcare providers as an aid in the diagnosis of Autism Spectrum Disorder (ASD) for patients ages 18 months through 72 months who are at risk for developmental delay based on concerns of a parent, caregiver, or healthcare provider.	Diagnosis	NA	2018	2020	202
EarliPoint System	EarliTec Diagnostics	FDA II	Cognoa ASD Diagnosis Aid	510k	K213882	2019	08.06.2022	Autism	Eye-tracking	ASD diagnosis or indeterminate diagnosis	The EarliPoint System is indicated for use in specialized developmental disabilities centers as a tool to aid clinicians in the diagnosis and assessment of Autism Spectrum Disorder (ASD) for patients ages 16 months through 30 months.	Diagnosis		NA	NA	NA
Ada Health App	AdaHealth	CE IIa	NA	NA	NA	2011	15.12.2022	Unspecific	Chatbot, Demographic	Most likely diagnoses	Ada takes the user through a comprehensive health assessment - starting with their basic demographic information, risk factors, and the symptom that's troubling them the most. Ada's AI-powered medical knowledge database determines the possible causes of the user's symptoms.	Diagnosis		2019	2022	NA
Limbic Access	Limbic AI	UKCA IIa	NA	NA	NA	2017	17.01.2023	Unspecific	Chatbot, Demographic	Most likely diagnoses, risk flagging, signposting	Limbic is an AI-powered triage assistant for mental healthcare. Its chatbot carries out a validated mental health screening to identify needs and support treatment decisions. Limbic may classify current mental health conditions, suggest interventions, and identify patients at risk for developing mental health conditions.	Diagnosis, patient referral		NA	NA	NA
PredictIX Digital	Taliaz	CE	NA	NA	NA	2012	01.12.2020	Depression	Demographic, Questionnaire, Clinical	Patient report with treatment recommendations	PREDICTIX Digital uses AI in combination with up-to-date clinical practice guidelines to analyze patients clinical and socio-demographic characteristics. The online tool yields a personalized patient report to support psychiatrist and GPs prescribing decisions. This ranks psychiatric drugs by predicted likelihood of patient's response and details associated side effects.	Psychopharmaca selection		NA	NA	NA

The identified products



Product fields

Diagnosis of Autism Spectrum Disorder Among Children Based on Behavioral Data



Diagnosis of Multiple Disorders Based on Conversational Data

Depression Medication Prescribing Based on Clinical and Genetic Data

Source: https://youtu.be/0uR5M7VpJ-w

Reasons for the lack of implementation of AI-CDSS into clinical practice

Reasons for the non-adoption of AI-CDSS in clinical practice

Data privacy and security

High costs, unclear gains

Interpretability and transparency

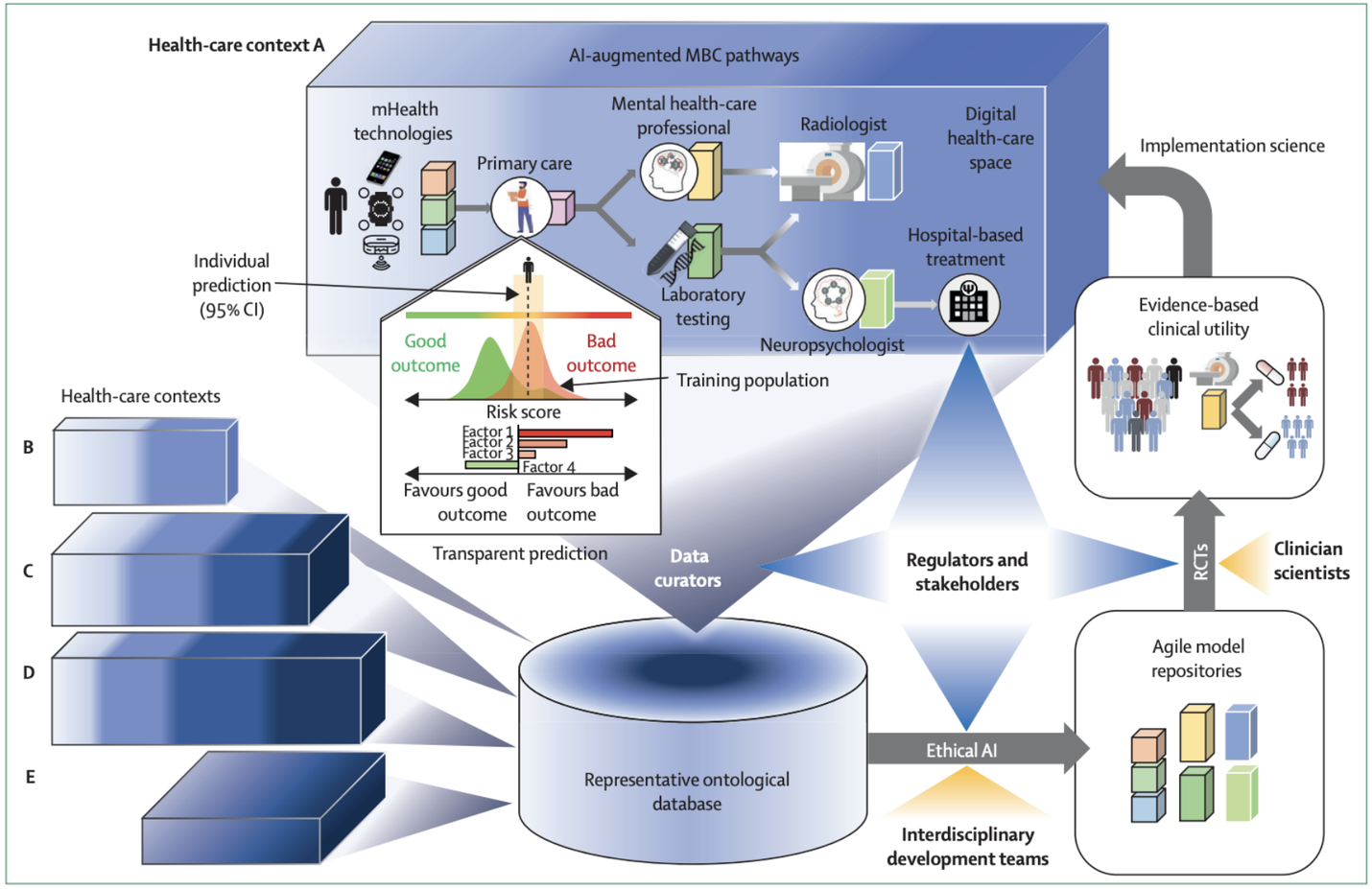
Integration issues

Regulatory challenges

Limited evidence on effectiveness

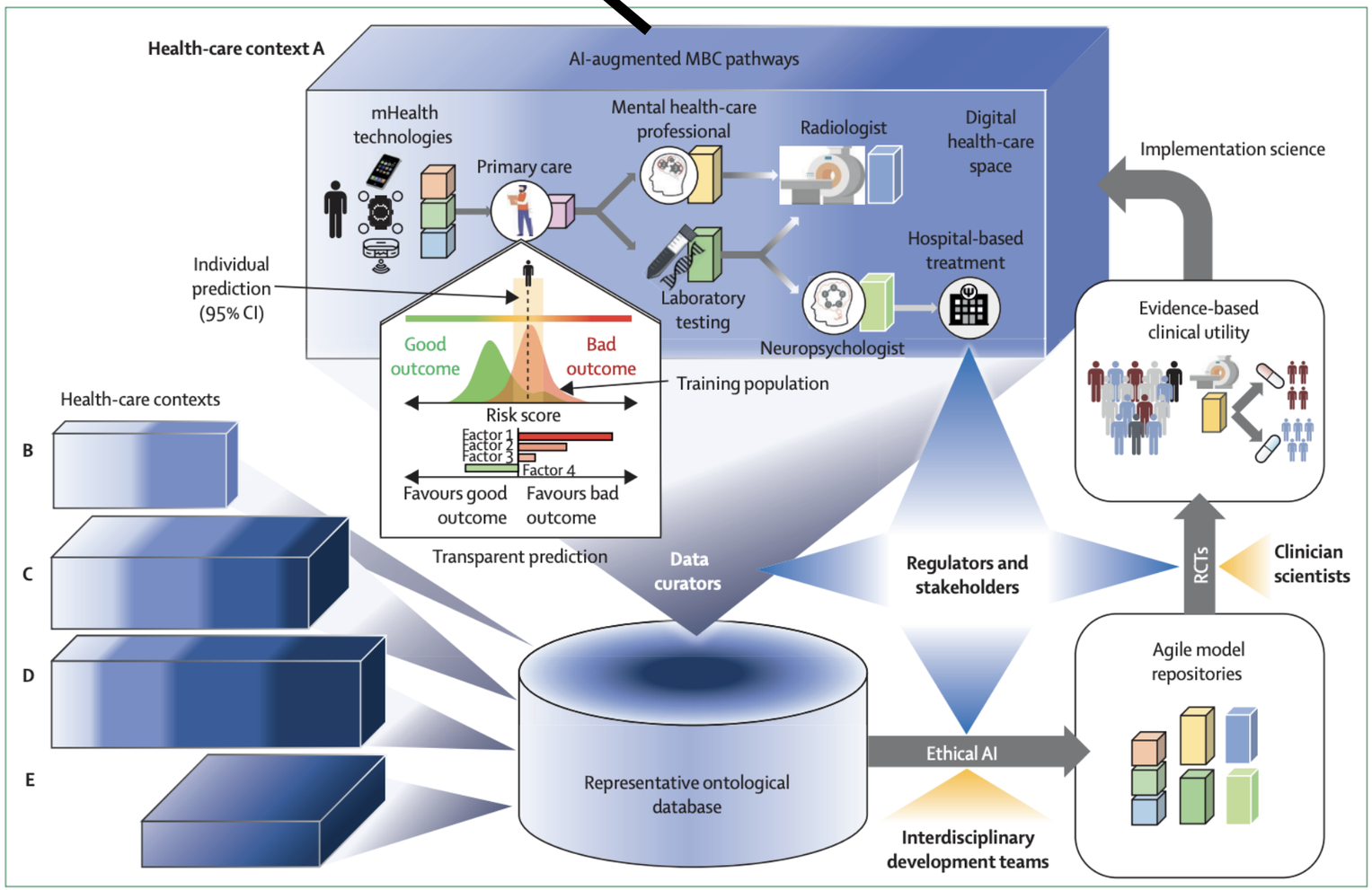
AI-informed healthcare: A system view

Koutsouleris et al. (2022). From promise to practice: Towards the realisation of AI-informed mental health care



Measurement-based care (MBC)

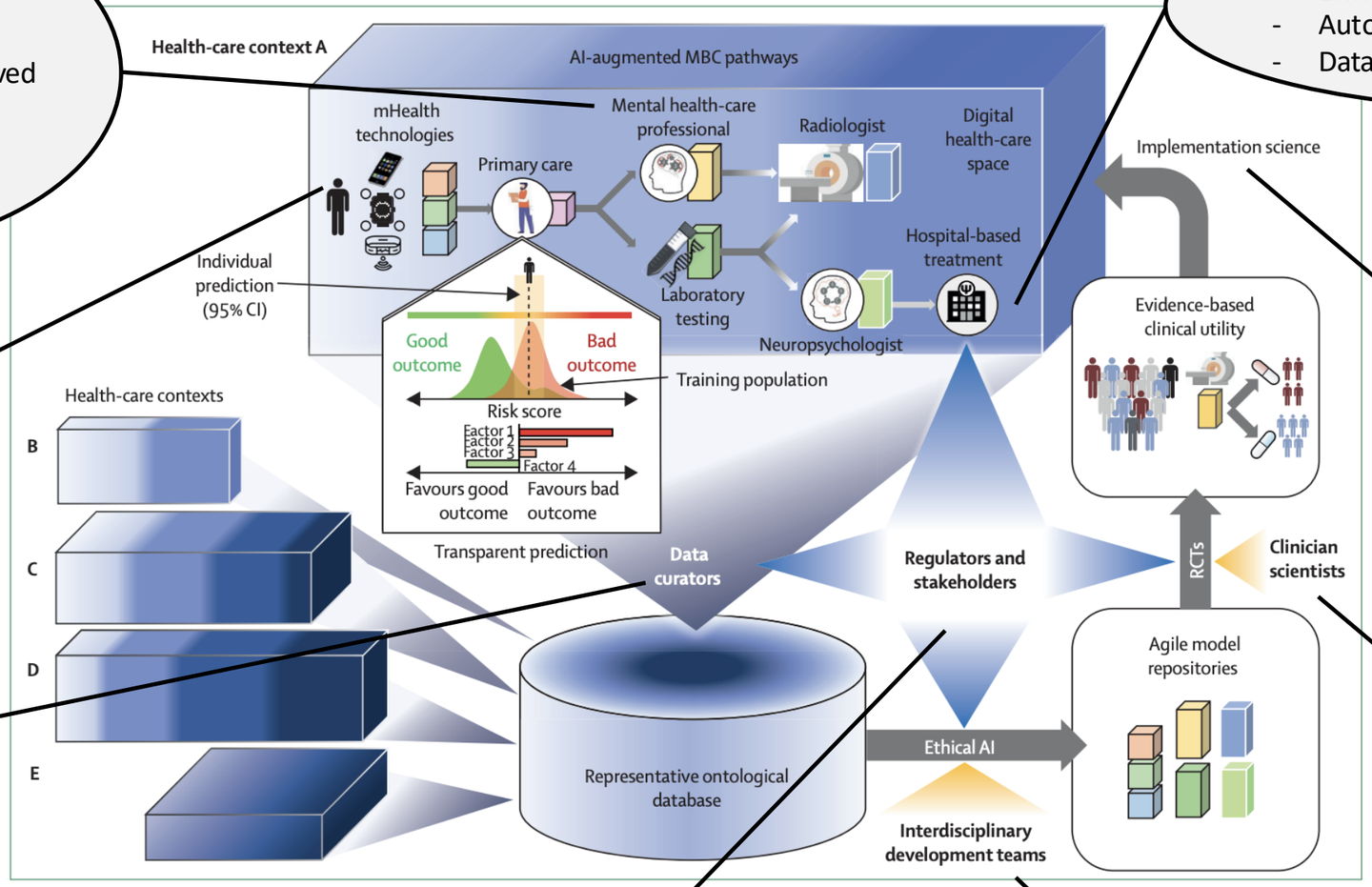
- Evidence-based practice where care providers systematically assess patient symptoms and use that information to inform treatment decisions



The different roles

HCPs
- Collect data
- Share feedback with the patient about data and observed or predicted trends to engage them in their treatment
- Act on these data

Institutions (e.g., hospitals)
- EHR systems
- Automated feedback systems
- Data collection and transfer systems



Patients
- Provide data

Implementation scientists
- Embed tools into health-space

Data curators
- Collect and clean the data
- Store data in ontological database

Clinician scientists
- Conduct RCTs to test clinical utility

Regulators and stakeholders
- Supervise the effects of AI-augmented health-care pathways on patients, data curation and model development, and the generation of model-based clinical evidence and implementation

AI development teams
- Develop AI solutions based on data
- Detect potential biases in data

takk for oppmerksomheten!

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clinaid-lab.com
annekathrinkleine.com

RESOURCES

Blanken, T. F., Benjamins, J. S., Borsboom, D., Vermunt, J. K., & Van Someren, E. J. W. (2020). Insomnia disorder subtypes and the role of hyperarousal. *Journal of Sleep Research*, *29*(SUPPL 1). Embase. https://doi.org/10.1111/jsr.13181

Boswell, J. F., Hepner, K. A., Lysell, K., Rothrock, N. E., Bott, N., Childs, A. W., Douglas, S., Owings-Fonner, N., Wright, C. V., Stephens, K. A., Bard, D. E., Aajmain, S., & Bobbitt, B. L. (2023). The need for a measurement-based care professional practice guideline. *Psychotherapy*, *60*(1), 1–16. https://doi.org/10.1037/pst0000439

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Kleine, A.-K., Lermer, E., Cecil, J., Heinrich, A., & Gaube, S. (2023). *Advancing Mental Health Care with AI-Enabled Precision Psychiatry Tools: A Patent Review*. PsyArXiv. https://doi.org/10.31234/osf.io/wmr38

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Research and Markets, Inc. (2022). *Precision Psychiatry Market—Global Industry Size, Share, Trends, Opportunity, and Forecast, 2017-2027*. TechSci Research. https://www.researchandmarkets.com/reports/5689413/precision-psychiatry-market-global-industry