Digital Health Technologies – What you need to know

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Washington, DC

Disclosure Information

- Sherry Nykiel, MD
  - Commercial Interests: No Disclosures
- Akiva Daum, MD
  - Commercial Interests: No Disclosures

Learning Objectives

- Explain the difference between digital health, digital medicine and digital therapeutics and be able to provide examples of each
- Identify the concerns surrounding privacy protections, research, reimbursement, health equity with the use of digital health technologies
- Create a plan to evaluate and incorporate digital health technologies into practice

Which is an example of a Digital Health Technology?

- Electronic Health Record
- Group therapy using telehealth
- Fitness watch
- Ecological Momentary Assessment
- EKG
- All of the above

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Digital Therapeutics require the same rigorous testing as other medical treatments

- True
- False

Digital Therapeutics require the same rigorous research as other medical treatments

- True
- False

Digital Health Information is secure

- True
- False

Digital Health Information is secure

- True
- False

Digital Therapeutics increase access to care

- True
- False

Digital Therapeutics increase access to care

- True
- False
- Maybe

Prescription Digital Therapeutics only require the prescriber to have health and technological literacy

- True
- False

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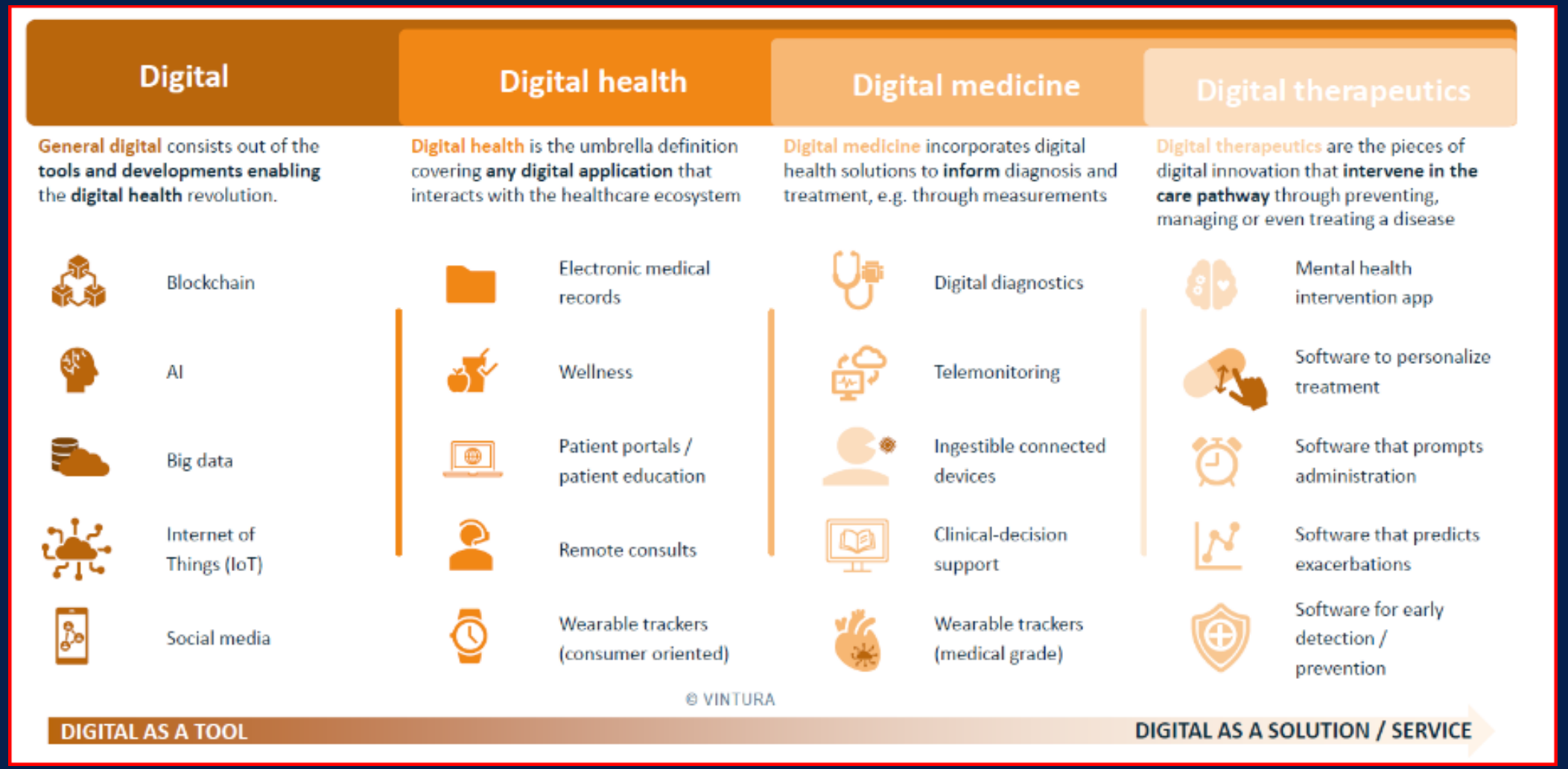
- True
- False

The Digital Continuum

The Digital Continuum



https://www.vintura.com/news/explaining-the-diversity-of-digital-health-solutions/

Digital Health

- "The use of digital technology and data analytics to understand people's health-related behavior and provide personal health care resources"

Marsch, L. A. (2020). Digital Health and Addiction. Current Opinion in Systems Biology, 20, 1–7. https://doi.org/10.1016/j.coisb.2020.07.004

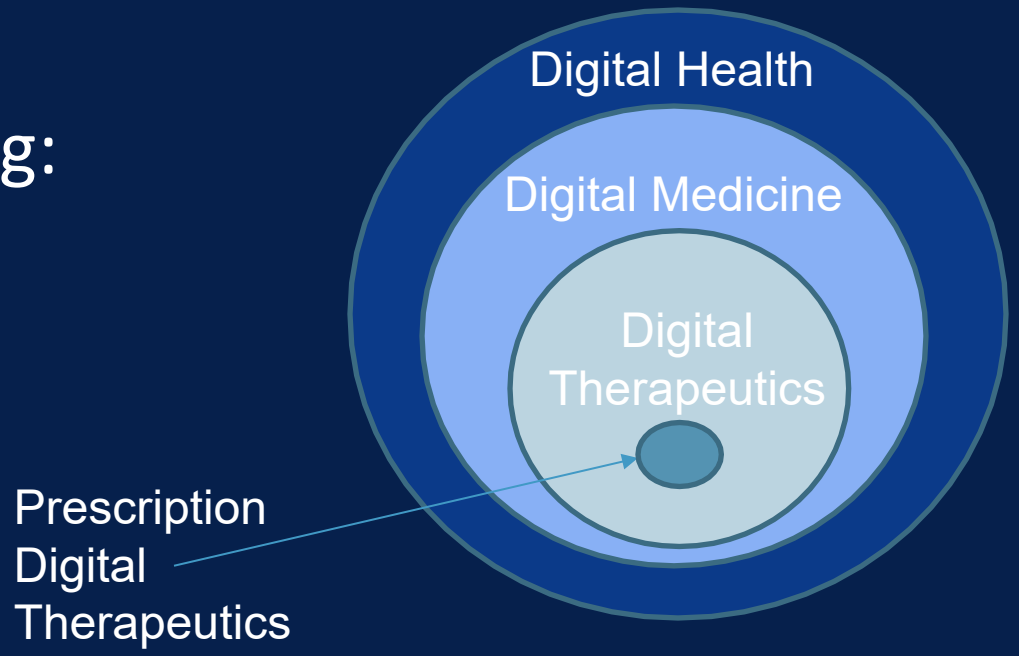
Digital Health

- "The use of digital technology and data analytics to understand people's health-related behavior and provide personal health care resources"
- Umbrella term encompassing Digital Medicine and Digital Therapeutics

Marsch, L. A. (2020). Digital Health and Addiction. Current Opinion in Systems Biology, 20, 1–7. https://doi.org/10.1016/j.coisb.2020.07.004

Digital Health Technology (DHT)

- "The use of digital technology and data analytics to understand people's health-related behavior and provide personal health care resources" [1]
- Umbrella term encompassing Digital Medicine and Digital Therapeutics
- Objectives of DHT include improving:
  - Population health
  - Patient and clinician experience
  - Clinical outcomes
  - Health disparities



[1] **Marsch, L. A.** (2020). Digital Health and Addiction. Current Opinion in Systems Biology, 20, 1–7. https://doi.org/10.1016/j.coisb.2020.07.004

Digital Health

- **Data & information capture, storage and display**
  - User facing technologies
    - Lifestyle apps, fitness trackers, nutrition apps, medication reminder apps, scheduling apps
  - Health Information Technology
    - Electronic Medical Record systems
    - Electronic prescribing
    - Computerized disease registries
  - Consumer health information
    - Patient portals
    - Personal health records

https://www.healthxl.com/blog/digital-health-digital-medicine-digital-therapeutics-dtx-whats-the-difference

Digital Health

- **Data & information transmission**
  - Telehealth
    - Telemedicine virtual visits
    - Remote care programs that do not include remote monitoring
  - Decision support software that:
    - Presents information for independent clinical review
    - Does not make recommendations that could not be found outside the software

https://www.fda.gov/media/109618/download

Digital Health

- **Data & information transmission**
  - Enterprise support
    - Clinical trial operation and management tools
  - Clinical care administration and management tools
    - Revenue cycle management tools
    - Clinical staffing management tools
    - Length of stay monitoring and management tools

https://www.healthxl.com/blog/digital-health-digital-medicine-digital-therapeutics-dtx-whats-the-difference

Digital Health Evidence and Oversite

https://www.utmedicalcenter.org/patients-visitors/clinical-trials/directory

Digital Medicine

- **"Digital medicine** describes a field, concerned with the use of technologies as tools for **measurement** and **intervention** in the service of human health."
- Play a direct role in *informing* diagnosis and treatment

Coravos, Andrea, et al. "Digital Medicine: A Primer on Measurement." *Digital Biomarkers*, vol. 3, no. 2, 2019, pp. 31–71

Digital Medicine

- **Measurement Products**
  - Digital diagnostics
  - Digital biomarkers
  - Remote patient monitoring

https://news.careinnovations.com/blog/what-is-telehealth-what-is-remote-patient-monitoring-how-are-they-different

Digital Medicine

- **Measurement and intervention products**
  - Digital companions
    - Ingestible sensors
    - Insulin pump

https://www.healthxl.com/blog/digital-health-digital-medicine-digital-therapeutics-dtx-whats-the-difference

Digital Medicine

- **Measurement and intervention products**
  - Digital products that both 1)measure and intervene and 2) do not require human intervention to serve primary purpose
    - CPAP
    - Artificial pancreas
    - Pacemaker
    - Cochlear implant

https://www.healthxl.com/blog/digital-health-digital-medicine-digital-therapeutics-dtx-whats-the-difference

Digital Medicine Evidence and Oversite

Clinical Evidence

https://www.utmedicalcenter.org/patients-visitors/clinical-trials/directory

Regulatory Oversite

Digital Therapeutics

- "Digital therapeutics deliver evidence-based therapeutic interventions to treat, manage or prevent a disease or disorder."
- "They are used independently or in concert with medications, devices or other therapies to optimize patient care and health outcomes."

https://dtxalliance.org/understanding-dtx/what-is-a-dtx/#difference

Digital Therapeutics Evidence and Oversite

- They diverge from the broader digital health market in that they must be approved by regulatory bodies and must provide evidence to support product claims of risk, efficacy and intended use.

Clinical Evidence

Regulatory Oversite

https://dtxalliance.org/understanding-dtx/what-is-a-dtx/#difference

Digital Therapeutics

- Per **industry standards**, digital therapeutic products should adhere to the following foundational principles:

https://dtxalliance.org/understanding-dtx/what-is-a-dtx/#difference

Digital Therapeutics

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? Which “industry” is setting the standards?

https://dtxalliance.org/understanding-dtx/what-is-a-dtx/#difference

Digital Therapeutics

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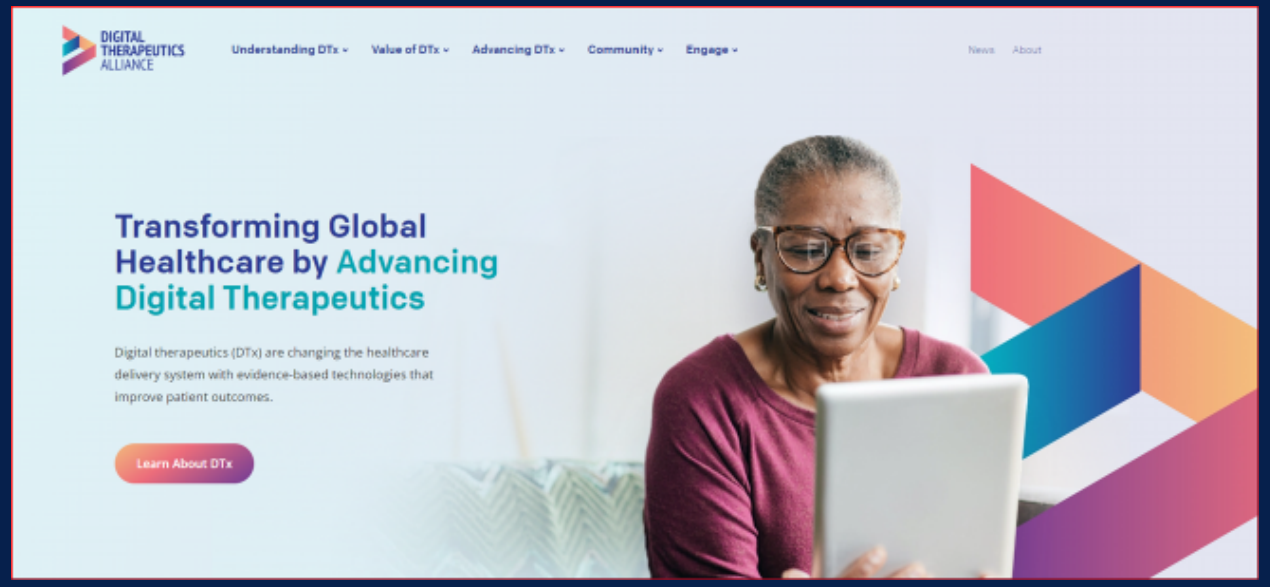
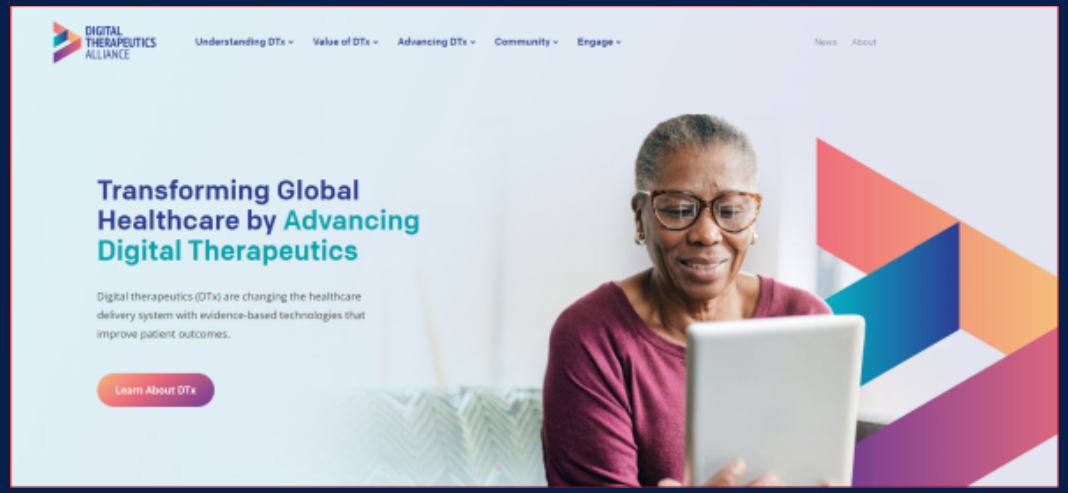


https://dtxalliance.org/understanding-dtx/what-is-a-dtx/#difference

Digital Therapeutics

”As the leading international organization on digital therapeutic thought leadership and education, the Digital Therapeutics Alliance provides **patients**, **clinicians**, **payors**, and **policymakers** with the necessary tools to evaluate and utilize DTx products.”



“Clinicians are integral to the development and utilization of digital therapeutic (DTx) products. DTA’s Clinician Advisory Group (CAG) is providing critical insight for the development of frameworks and publications to enable more consistent evaluation, authorization, and use of DTx products in clinical care.”

https://dtxalliance.org/

Digital Therapeutics

- Per **industry standards**, digital therapeutic products should adhere to the following foundational principles:
  1. Treat, manage, or prevent a disease or disorder.
  2. Produce a medical intervention that is driven by software.
  3. Incorporate design, manufacturing, and quality best practices.
  4. Engage end users in product development and usability processes.
  5. Incorporate patient privacy and security protections.

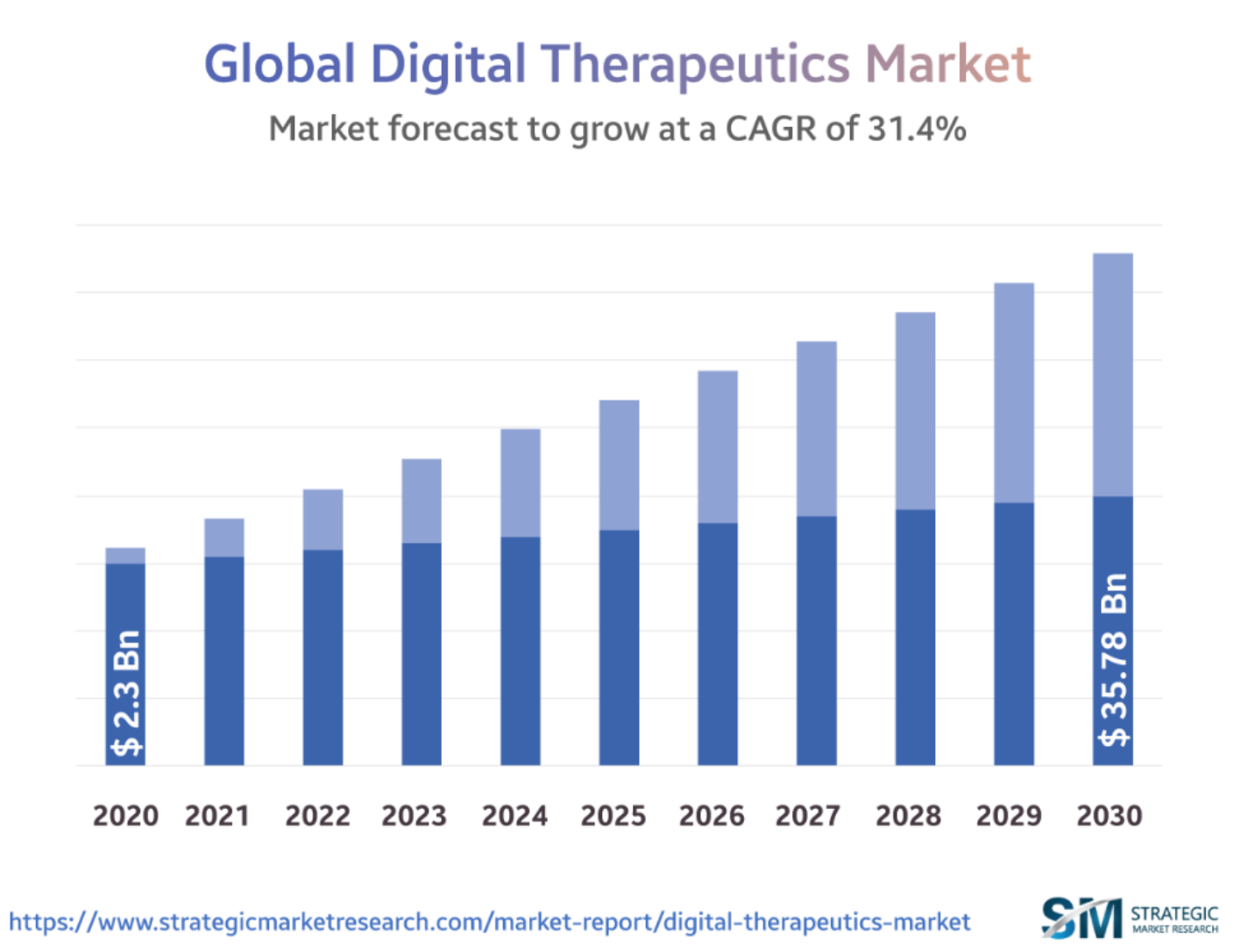
https://dtxalliance.org/understanding-dtx/what-is-a-dtx/#difference

Digital Therapeutics

- Per industry standards, digital therapeutic products should adhere to the following foundational principles:
  6. Apply product deployment, management, and maintenance best practices.
  7. Publish trial results inclusive of clinically meaningful outcomes in peer-reviewed journals.
  8. Be reviewed and cleared or certified by regulatory bodies as required to support product claims of risk, efficacy, and intended use.
  9. Make claims appropriate to clinical evaluation and regulatory status.
  10. Collect, analyze, and apply real-world evidence and/or product performance data.

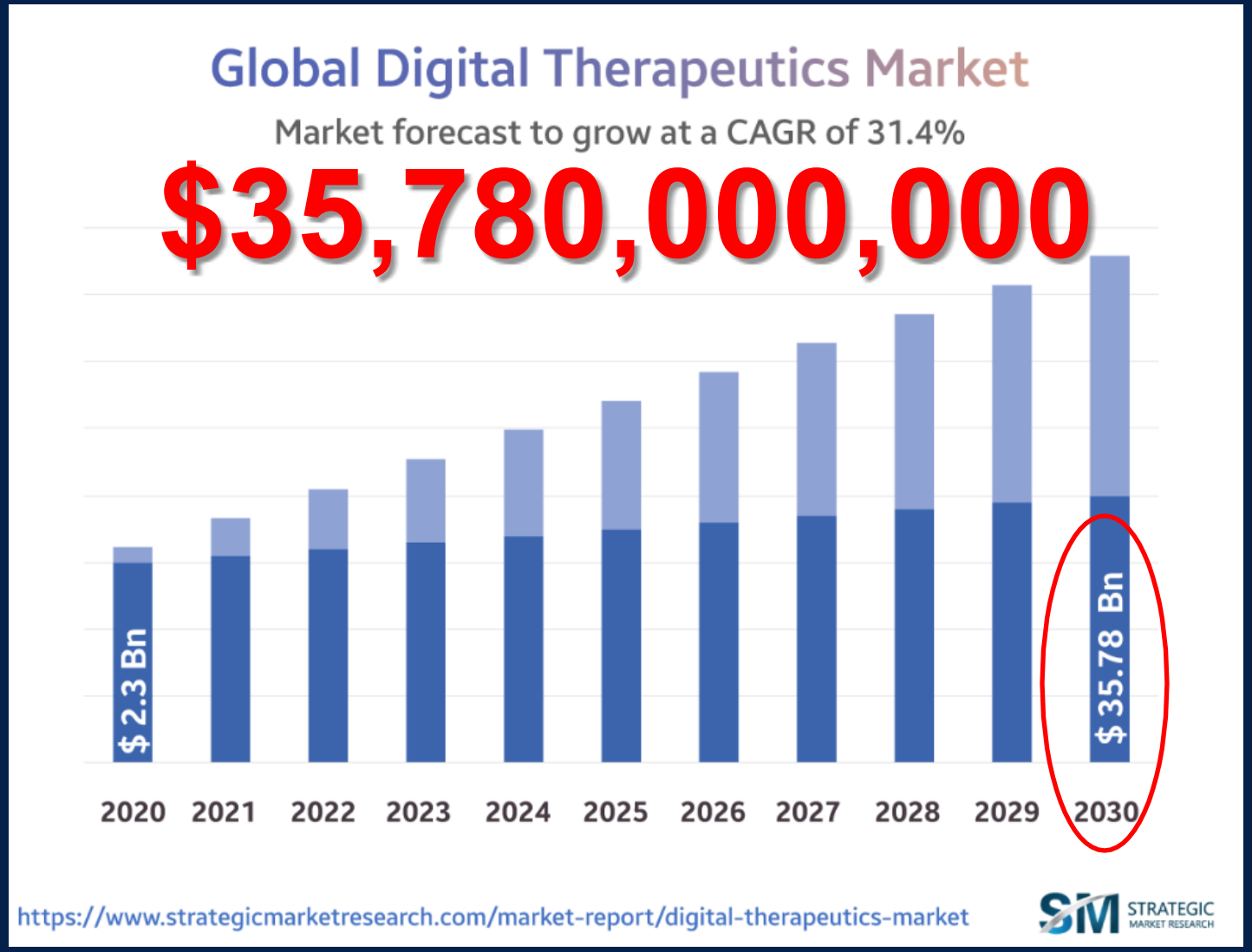
https://dtxalliance.org/understanding-dtx/what-is-a-dtx/#difference

Digital Therapeutics

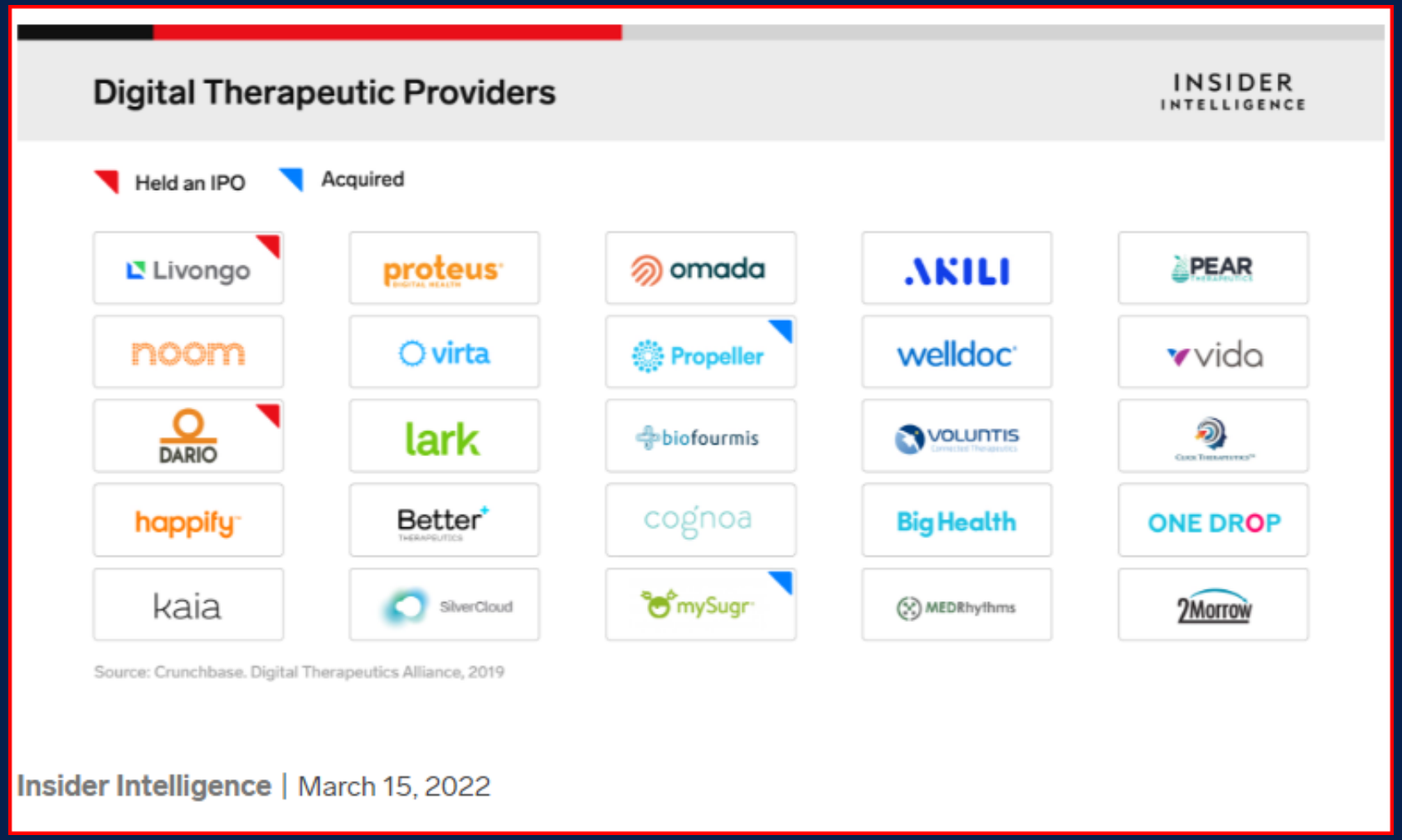


AMERICAN SOCIETY OF ADDICTION MEDICINE FOUNDED 1954 ASAM

Digital Therapeutics

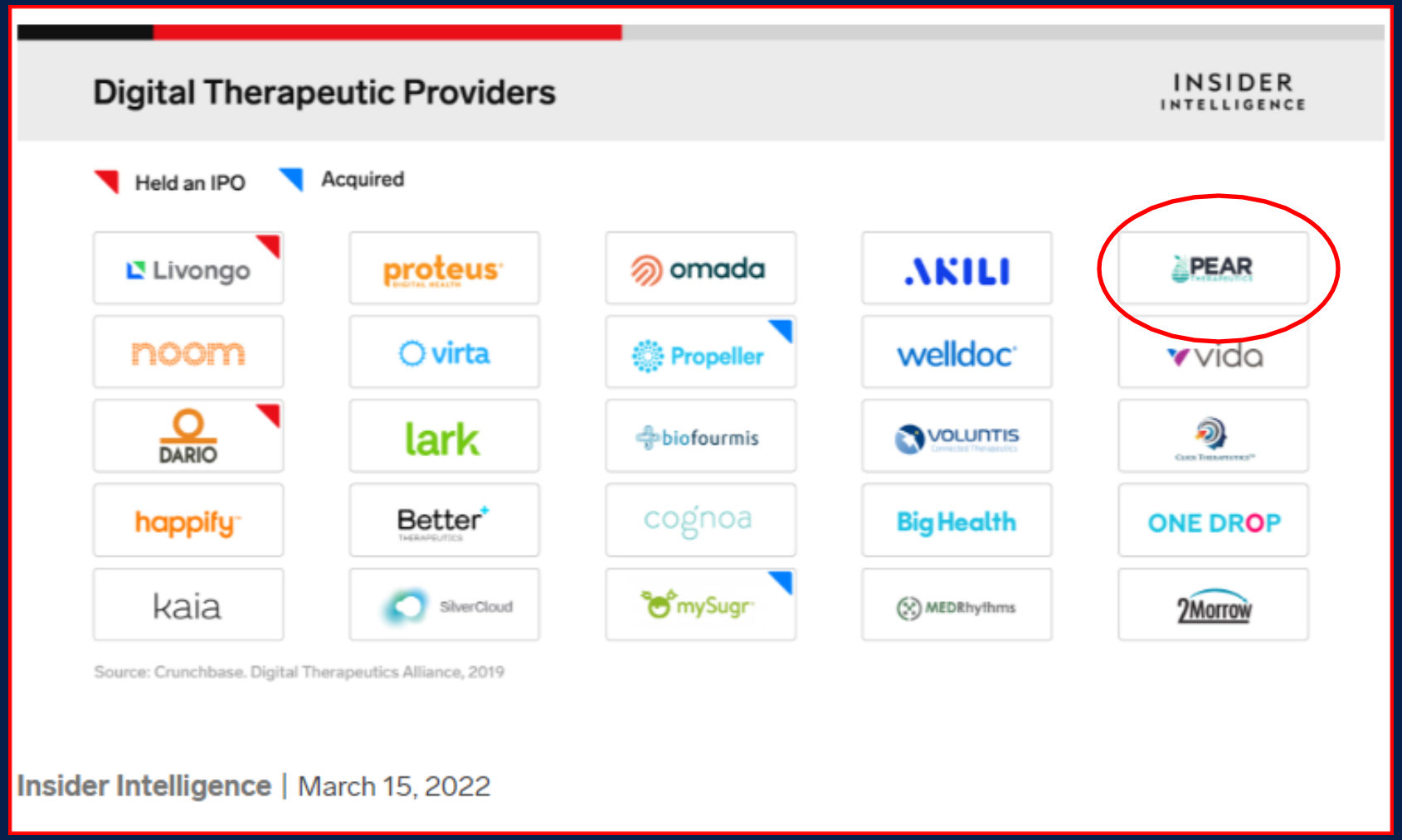


Digital Therapeutic Providers



https://www.insiderintelligence.com/insights/digital-therapeutics-report/

Prescription Digital Therapeutics



https://www.insiderintelligence.com/insights/digital-therapeutics-report/

Prescription Digital Therapeutics

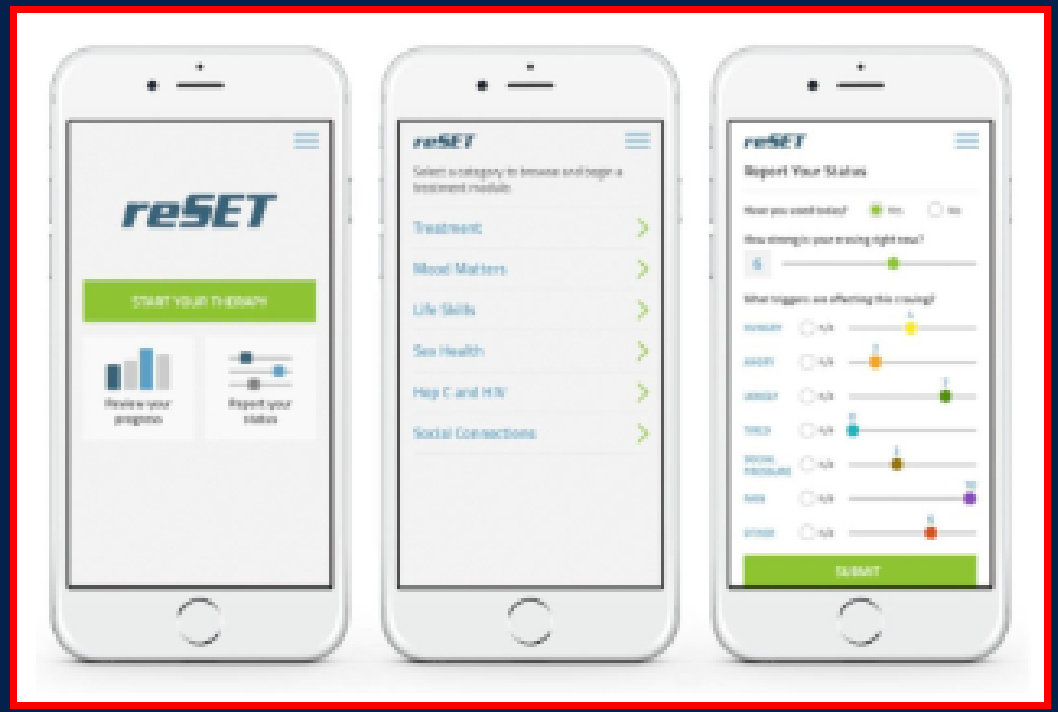
Pear Therapeutics gets de novo FDA clearance for reSET, a digital therapeutic for substance abuse

By **Jonah Comstock** | September 14, 2017 | 03:33 pm

SHARE

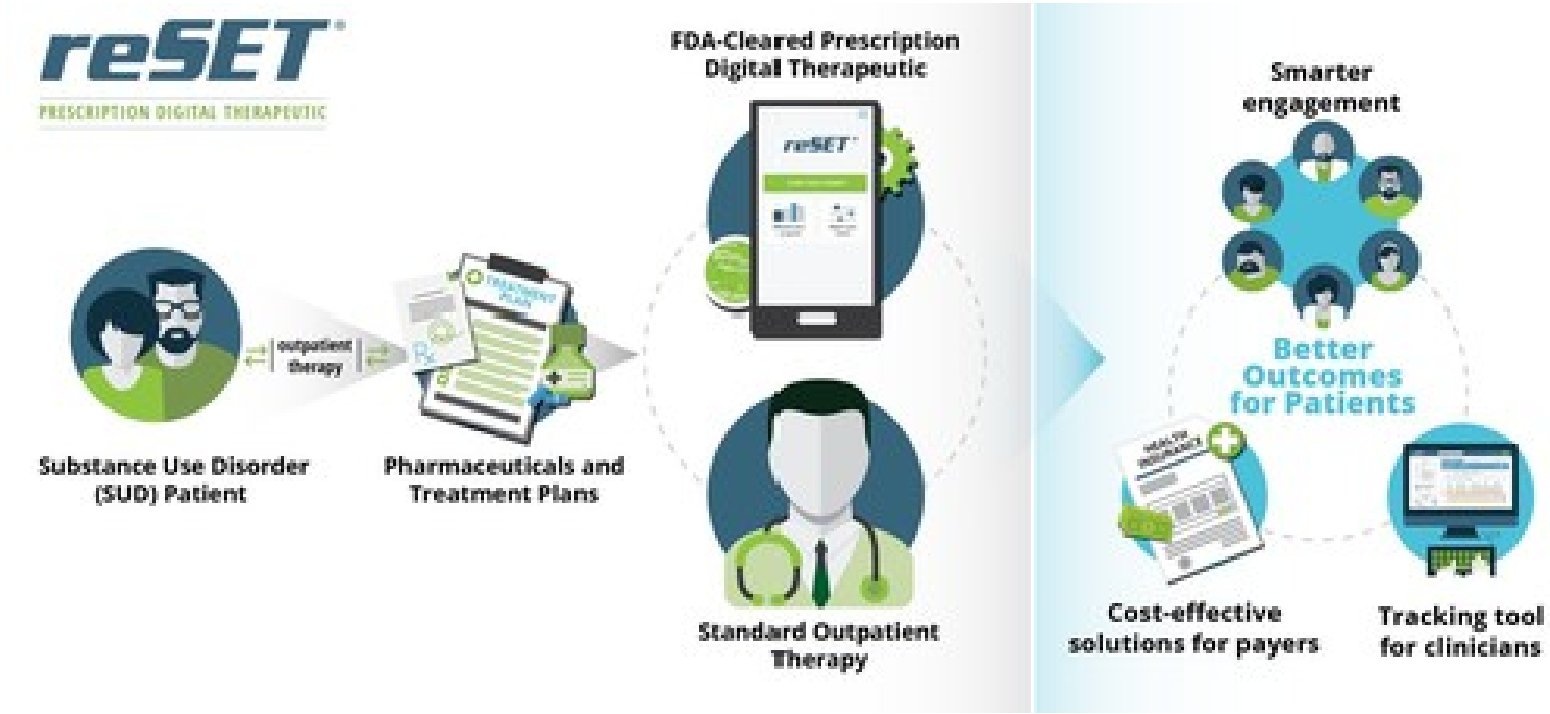
In an FDA first, Boston- and San Francisco-based Pear Therapeutics' reSET system for the treatment of substance abuse has been granted a de novo clearance by the agency. It's the first software-only digital therapeutic the FDA has cleared with claims to improve clinical outcomes in a disease.

"This is a defining moment for digital therapeutics and for patients with substance use disorder," Corey McCann, president and CEO of Pear Therapeutics said in a statement. "As the first FDA-cleared Prescription Digital Therapeutic for disease treatment, reSET has demonstrated improved abstinence and treatment retention in a randomized controlled clinical study. We believe that prescription digital therapeutics hold promise in improving patient outcomes across a wide range of central nervous system disorders including psychiatry, neurology, and pain, and will become a vital part of tomorrow's treatment paradigm across all disease areas. Pear was impressed by the collaborative approach the FDA took in reviewing this innovative technology."



https://www.mobihealthnews.com/content/pear-therapeutics-gets-de-novo-fda-clearance-reset-digital-therapeutic-substance-abuse

Prescription Digital Therapeutics



https://www.prnewswire.com/news-releases/pear-therapeutics-obtains-fda-clearance-of-the-first-prescription-digital-therapeutic-to-treat-disease-300520068.html


FDA Approved

FDA Approval

- Pear got reSET approved by the FDA by putting it on a regulatory pathway at the agency known as “de novo classification process”
  - created in 1997 for novel medical devices posing low to moderate risk.
- Current use of FDA approved PDTs, including reSET and reSET-O, either as a standalone or adjunctive treatment is considered investigational

https://www.managedhealthcareexecutive.com/view/digital-therapeutics-shaping-the-future-of-care

FDA Approval

www.fda.gov/drugs/information-drug-class/timeline-selected-fda-activities-and-significant-events-addressing-substance-use-and-overdose.

FDA Approval

FDA U.S. FOOD & DRUG ADMINISTRATION

Search Menu

Home / Drugs / Drug Safety and Availability / Information by Drug Class / Timeline of Selected FDA Activities and Significant Events Addressing Substance Use and Overdose Prevention

Timeline of Selected FDA Activities and Significant Events Addressing Substance Use and Overdose Prevention

Chronological information about significant FDA activities related to substance use and overdose prevention

1995

December: OxyContin (oxycodone controlled-release) approved; first formulation of oxycodone that allowed dosing every 12 hours instead of every 4 to 6 hours. OxyContin would soon become a focal point of opioid abuse issues that would continue to escalate into the late 2000s and beyond.

www.fda.gov/drugs/information-drug-class/timeline-selected-fda-activities-and-significant-events-addressing-substance-use-and-overdose.


Exposed record
Data breach
Protection
anonymous
law
Metadata
Regulations
DATA
PRIVACY
classification
digital
Search
Patient privacy
Privacy
Risk
Sensitive Information
Authentication
compliance

Privacy, Confidentiality & Cybersecurity

- *"Our AMA encourages physicians to alert patients to the potential privacy and security risks of any mHealth apps that he or she prescribes or recommends, and document the patient's understanding of such risks" (AMA Policy H-480.943)*

"Policy Finder | AMA." *Ama-Assn.org*, 2023, policysearch.ama-assn.org/policyfinder/detail/mobile%20health?uri=%2FAMADoc%2FHOD-480.943..xml.

Privacy, Confidentiality & Cybersecurity

December 2020

Perspectives in Health Information Management

American Health Information Management Association

Current Challenges with Digital Data and Privacy

Emerging technologies such as genealogical databases (i.e. 23andme and Ancestry) as well as wearable devices and mHealth apps have created a new risk for data privacy that is not covered by HIPAA. These digital health tools are not covered entities therefore they are not required to protect the data they collect under HIPAA. The Department of Health and Human Services nor the Office of Civil Rights have purview over this data or any breach of the consumer's information. Any complaint regarding a breach of consumer's health data is rejected, as there is no controlling law currently for this type of data. Complaints of this type go to the Federal Trade Commission; however, many consumers are never aware that their information is breached, shared or sold to a third party because there is no breach notification requirement in place.

Theodos K, Sittig S. Health Information Privacy Laws in the Digital Age: HIPAA Doesn't Apply. *Perspect Health Inf Manag*. 2020;18(Winter):1l. Published 2020 Dec 7.

Privacy, Confidentiality & Cybersecurity

February 2023

ETHICAL ISSUES

Now for sale: Data on your mental health

Capitalizing on the pandemic explosion in telehealth and therapy apps that collect details of your mental health needs, data brokers are packaging that information for resale, a new study finds. There's no law stopping them.

By Drew Harwell

February 13, 2023 at 6:00 a.m. EST

The Washington Post
Democracy Dies in Darkness

A researcher tried to buy mental health data. It was surprisingly easy.

NBC NEWS

A Duke University report found 11 data brokers agreed to sell information that identified people by issues, including depression, anxiety and bipolar disorder, and often sorted them by demographic information.

Feb. 13, 2023, 9:49 AM EST

By Kevin Collier

SC MEDIA

Privacy, Data security, Third-party risk

Lack of consumer privacy protections allows data brokers to sell mental health info

Jessica Davis February 15, 2023

KTRH Local Houston and Texas News

Report: Data Brokers Selling Mental Health Information

By Nik Rajkovic

Feb 22, 2023

POLITICOPRO

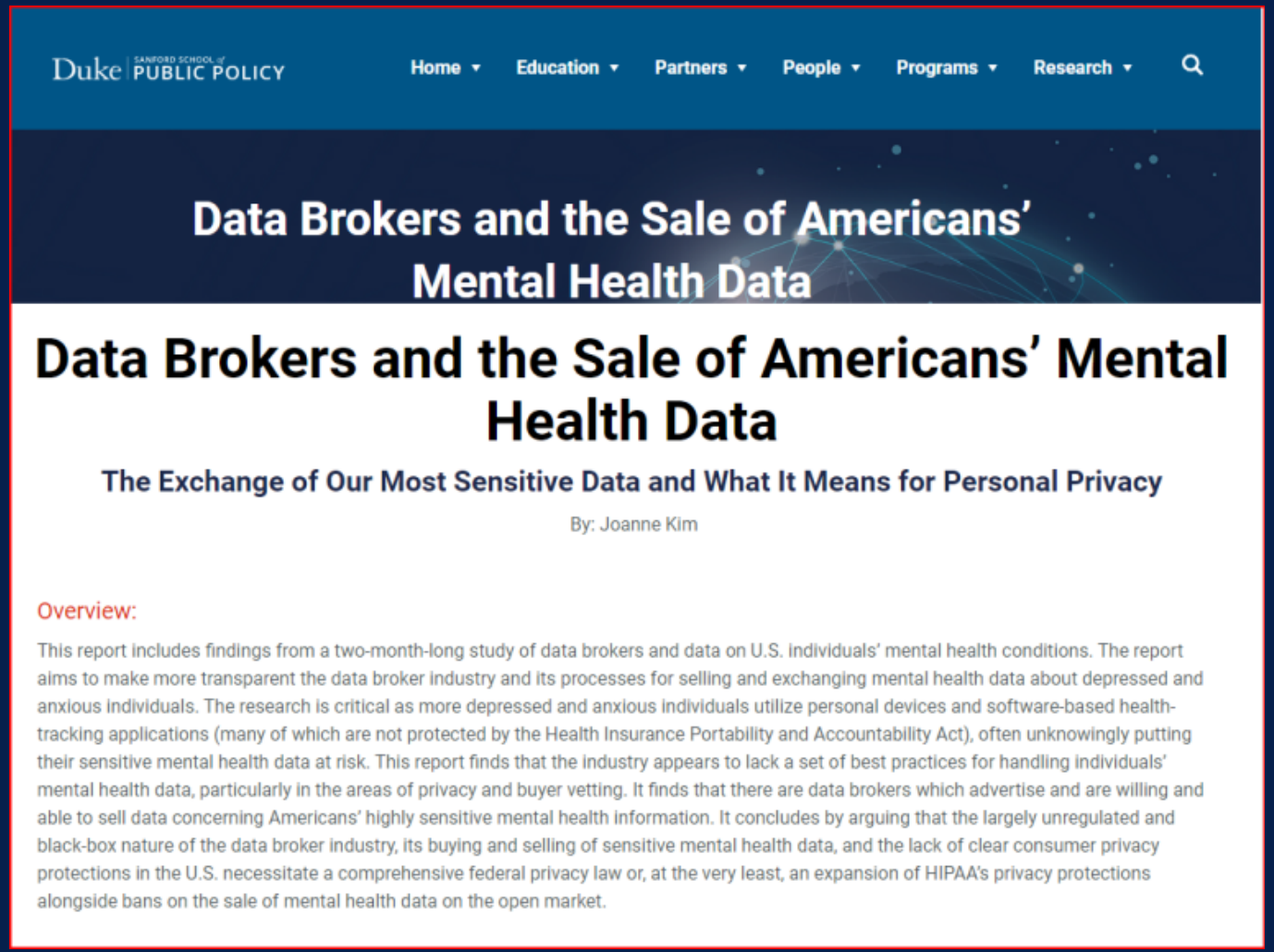
PRO NEWS

Data broker marketplace research shows loose controls on sensitive mental health info

American Society of Addiction Medicine
Founded 1954
ASAM

Privacy, Confidentiality & Cybersecurity

February 2023



"Data Brokers and the Sale of Americans' Mental Health Data - Tech Policy @ Sanford." *Tech Policy @ Sanford*, 13 Feb. 2023, techpolicy.sanford.duke.edu/data-brokers-and-the-sale-of-americans-mental-health-data/.

Privacy, Confidentiality & Cybersecurity

"Since most mHealth apps are not covered by the Health Insurance Portability and Accountability Act (HIPAA), which only applies to certain covered health entities, many private companies operating mHealth apps are not legally obligated by HIPAA to keep their users' data confidential."

"Consequently, mHealth apps, wearables, social media platforms, and many other technology companies (collectively referred to as "emerging mHealth technologies") can most often legally share, license, and sell users' health data (in addition to other data) to third parties without users' knowledge or consent"

"Data Brokers and the Sale of Americans' Mental Health Data - Tech Policy @ Sanford." *Tech Policy @ Sanford*, 13 Feb. 2023, techpolicy.sanford.duke.edu/data-brokers-and-the-sale-of-americans-mental-health-data/.

Privacy, Confidentiality & Cybersecurity

This Privacy Policy covers how Pear Therapeutics, collects, receives, uses, retains, and discloses Personally Identifiable Information ("PII") of Clinicians (also "you", "your" or "user") through the Site.
PII includes information about you that is personally identifying such as your name, email address, and phone number and which is not otherwise publicly available. Only the legal definition of PII that applies to your location will apply to you under this Privacy Policy.

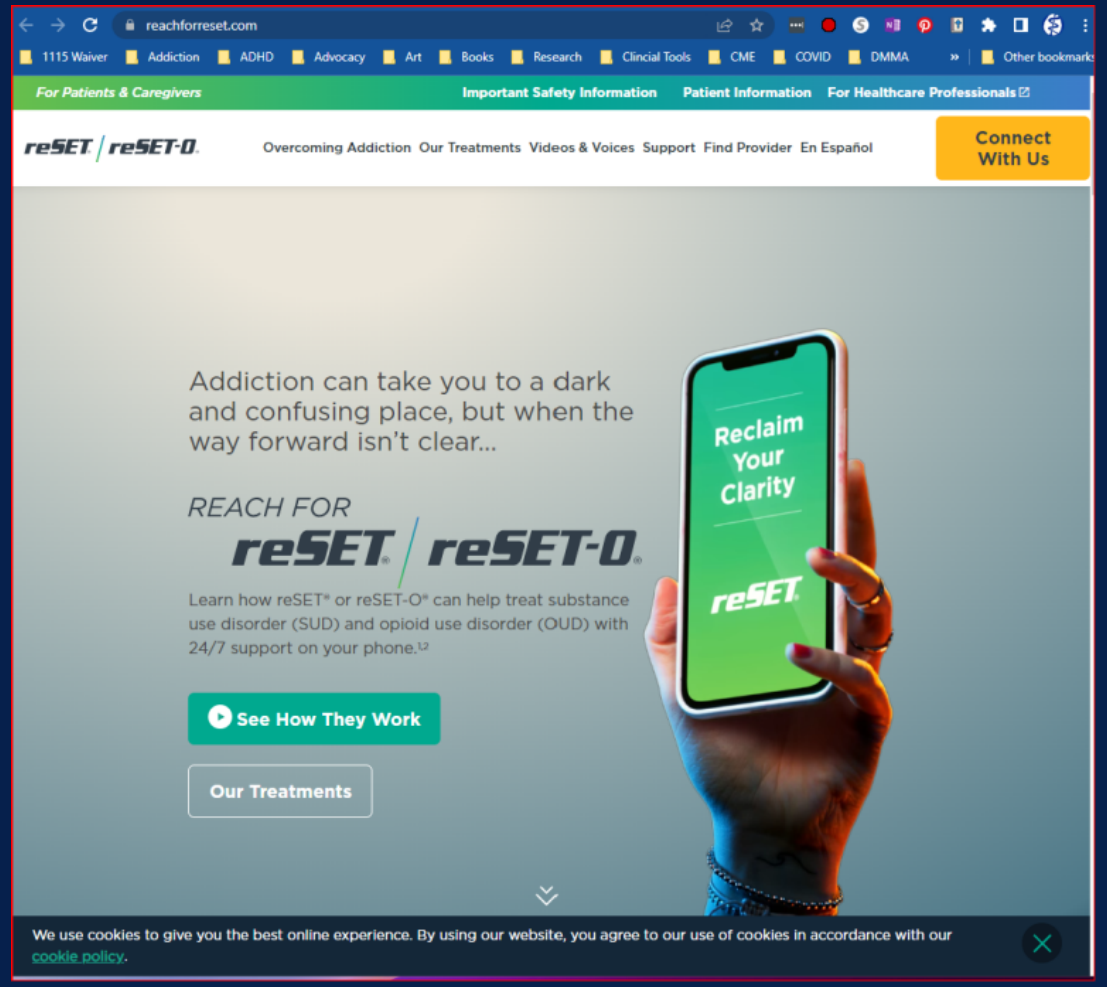
When you use the Site or the Service, we use tracking technology to collect de-identified information relating to your browser or device type, the time and date you use the Service, operating system, identification of Site page views, use of particular Service features, geographic location and other statistical information relating to your use of the Site or the Service but which does not identify you. This information is referred to in this Privacy Policy as "Analytics." We use Analytics to develop, improve, extend and test the Service (and underlying technology platforms); to market and promote Pear Therapeutics and the Service; and we disclose, distribute and transmit Analytics to Clinical Partners for their use.

Agreement

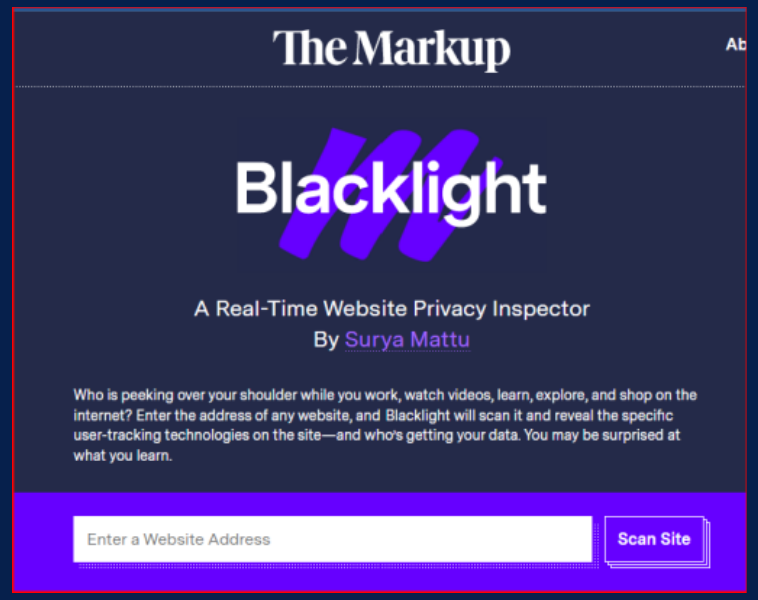
By using the Site or the Service, and/or by providing PII to Pear Therapeutics, you accept and hereby expressly consent to our collection, use, retention, and disclosure of your PII in accordance with the terms of this Privacy Policy. If you choose not to provide the requested information you will not be able to access the Site or Service.

This Privacy Policy may change from time to time, so please check back periodically to check the most recent modification date to ensure that you are aware of any changes in our processing of your Personal Data. Your continued use of the Site or the Service after any changes signifies your express, explicit, voluntary and unambiguous consent to any such changes. If you do not agree to such changes, you must immediately stop using the Site. This Privacy Policy was last modified on January 18, 2017.

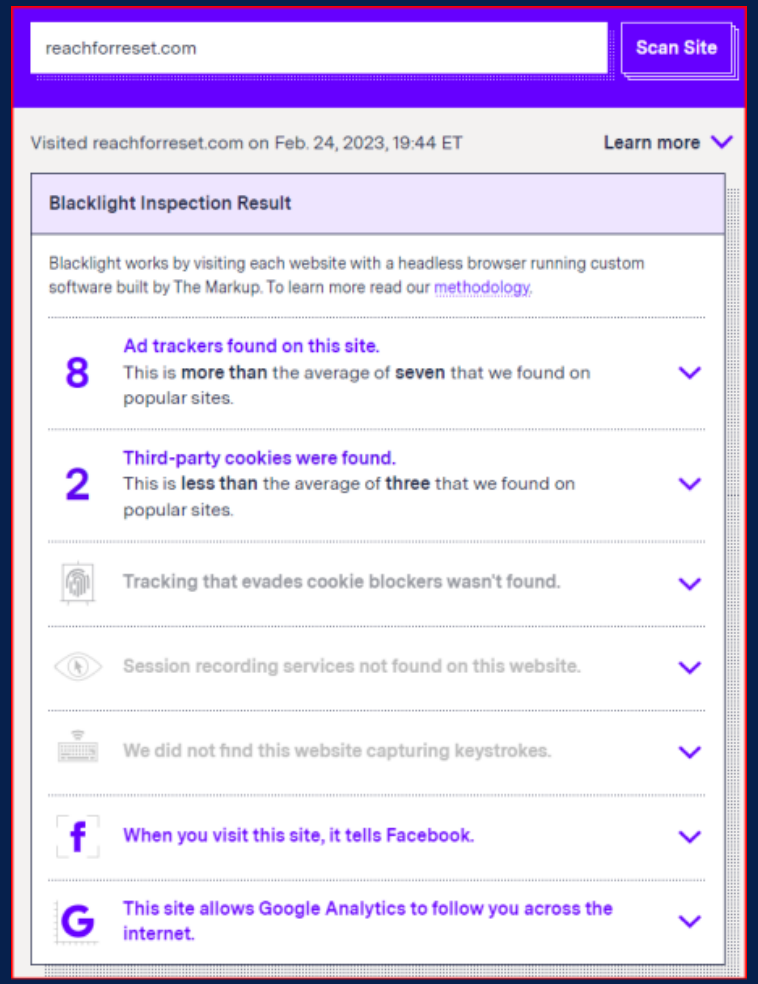
https://peartherapeutics.com/privacy-policy/

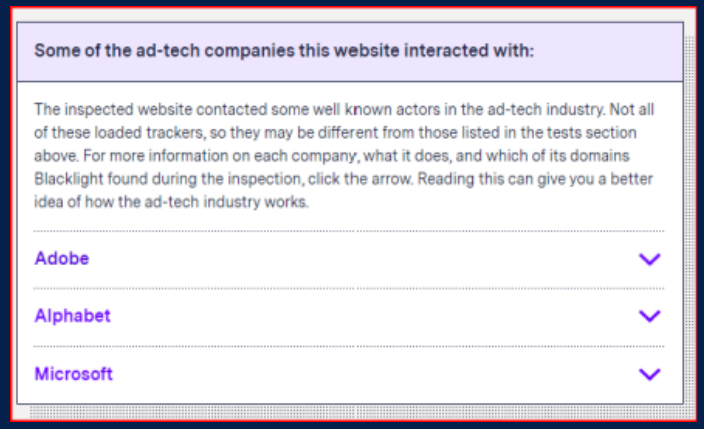


Privacy, Confidentiality & Cybersecurity

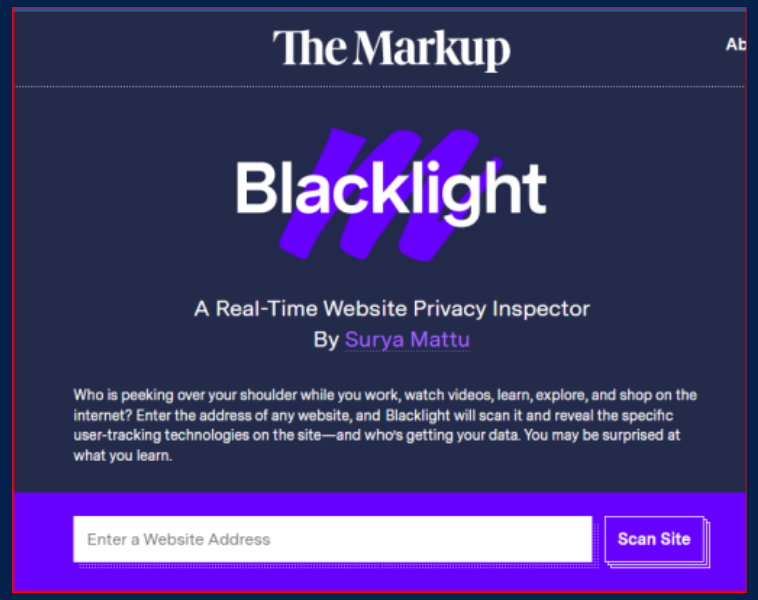


https://themarkup.org/blacklight





Privacy, Confidentiality & Cybersecurity



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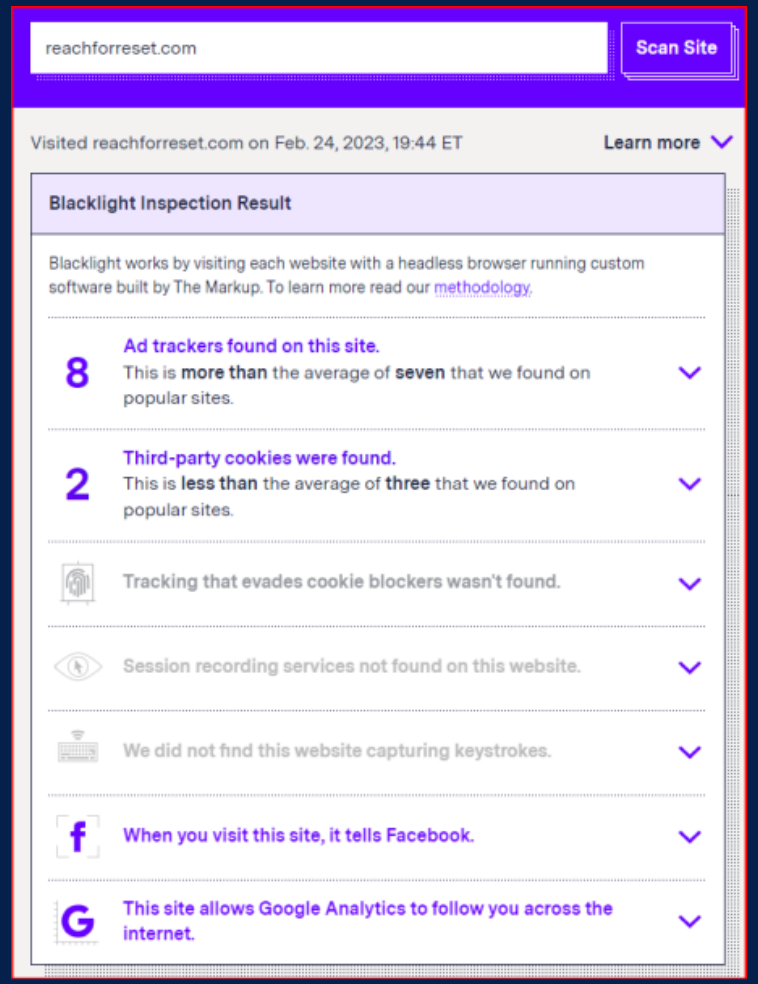

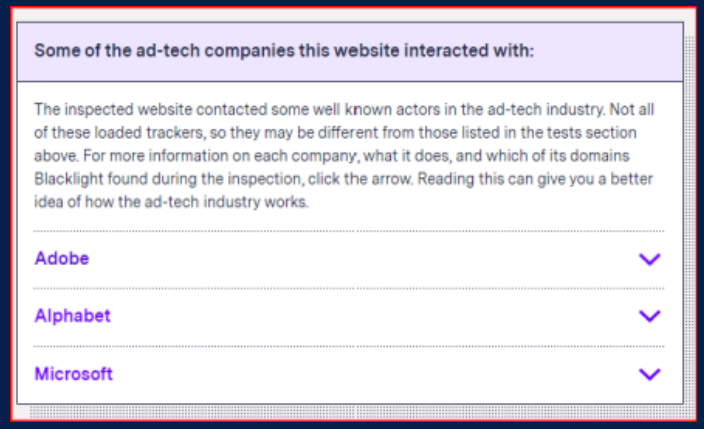

https://www.lac.org/resource/the-fundamentals-of-42-cfr-part-2


RESEARCH
WORK
RESULTS
DEVELOPMENT
DISCOVERY
EXPLANATION
ANALYSIS
SCIENCE
KNOWLEDGE
DATA
METHODS
EVIDENCE
SYSTEMS
EXPERIMENTAL
CURIOSITY
UNKNOWN
DOCUMENTATION
INNOVATION
INFORMATION
NEW
EXPLORE
MANAGEMENT
STUDY
PRACTICE
MARKETING
MODEL

Research

- The randomized controlled trial (RTC) is the most rigorous method of testing available and is considered the gold standard trial for evaluating the effectiveness of interventions

- PDTs which are based on software require creating the equivalent of a placebo
  - *"It may be challenging to construct a placebo control that appears to function like the investigational device but delivers no therapy."* (FDA Final Guidance Document "Design Considerations for Pivotal Clinical Investigations for Devices" 2013).

https://www.brainsway.com/knowledge-center/the-placebo-effect-medication-and-mental-health

Research

- Lutz et.al. recently published a review of clinical RCTs that used psychosocial, cognitive or behavioral interventions
  - The control conditions used when studying pharmaceuticals or medical devices may not directly apply to the study of PDTs
  - Control condition nomenclature across studies was inconsistent and clear descriptions of control interventions were missing in most cases, which limits the ability to compare results across studies
  - Considerable heterogeneity observed in the literature

Lutz, Jacqueline, et al. "Appropriate Controls for Digital Therapeutic Clinical Trials: A Narrative Review of Control Conditions in Clinical Trials of Digital Therapeutics (DTx) Deploying Psychosocial, Cognitive, or Behavioral Content." *Frontiers in Digital Health*, vol. 4, 18 Aug. 2022

Research

- Demand has outpaced the research
- Most studies are industry funded and conducted by the developers leading to concerns for funding bias
  - In the case of reSET and reSET-O, the majority of research published was done by current or former employees of Pear Therapeutics or paid for by the company
- More independent studies are needed to demonstrate the effectiveness of these interventions using consistent and replicable research standards
- These interventions must be subject to the same rigorous research standards used for other treatments such as pharmaceuticals


Equity

Health Equity

- Use of PDT has potential advantages
  - increased access to care
  - decreased informational barriers
  - opportunity for patient self-management
  - improved communications with providers

Hamideh, D., & Nebeker, C. (2020). The digital health landscape in Addiction and substance use research: Will digital health exacerbate or mitigate health inequities in vulnerable populations? Current Addiction Reports, 7(3), 317–332

Health Equity

- Use of PDT has the potential to worsen already devasting healthcare inequalities
  - Lack of inclusion of vulnerable and historically underrepresented populations in digital health research
  - Lack of reliable internet
  - Inadequate digital literacy
  - Lack of private, safe space
  - Lack of evidence-based clinical guidance on which patients would benefit most and which may be harmed with the widespread use of PDTs

Garett, Renee, and Sean D. Young. "Potential Effects of Digital Inequality on Treatment Seeking for Opioid Use Disorder." *International Journal of Mental Health and Addiction*, 27 Aug. 2021


PRESCRIPTION
For:
Address:
Rx
Date
M.D.

Prescriber Logistics

- No formal curriculum or training programs to assure competency in digital healthcare
- No standardized, evidenced based workflows for implementation and on-going prescribing
- Uninformed prescribing complicates gathering of reliable data
- Given lack of concrete legal and regulatory guidance regarding privacy, providers who prescribe PDT may be releasing patient data in violation of HIPPA

Ronquillo, Yasmyne, et al. “Digital Health.” *Nih.gov*, StatPearls Publishing, 8 May 2022, www.ncbi.nlm.nih.gov/books/NBK470260


HEALTH INSURANCE CLAIM
POLICYHOLDER'S DETAILS
Insurance number
First name(s)/surname/title
Date of birth
Correspondence address
Postcode and town
Phone (+country code and local dialing code)
PATIENT'S DETAILS
Insured's or co-insured's number
Date of birth
In case of an accide
REIMBURSEMENT
Currency of payment
Payment me
Payment by
Bank name
Branch code (BLZ, ABA, sort code)
BIC/SWIFT code
Payment via bank account
Country
PATIENT'S SIGN
I hereby certify th
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Reimbursement

- CMS has yet to issue a national coverage determination and as such no Medicare benefit category or physician fee schedule exists
- Billing with CPT codes only covers the cost of clinician time and services and not the cost of the PDT
- CMS recently implemented a Level II Healthcare Common Procedure Coding System (HCPCS) code, A9291, for "prescription digital behavioral therapy, FDA cleared, per course of treatment."
  - Using a code with such a broad indication does not consider that PDTs differ in indication, sophistication and time needing to administer and treat.
  - Without individual HCPCS codes for each PDT, payment may not cover the cost of administering the treatment
- There is very little cost data to be able to determine appropriate reimbursement

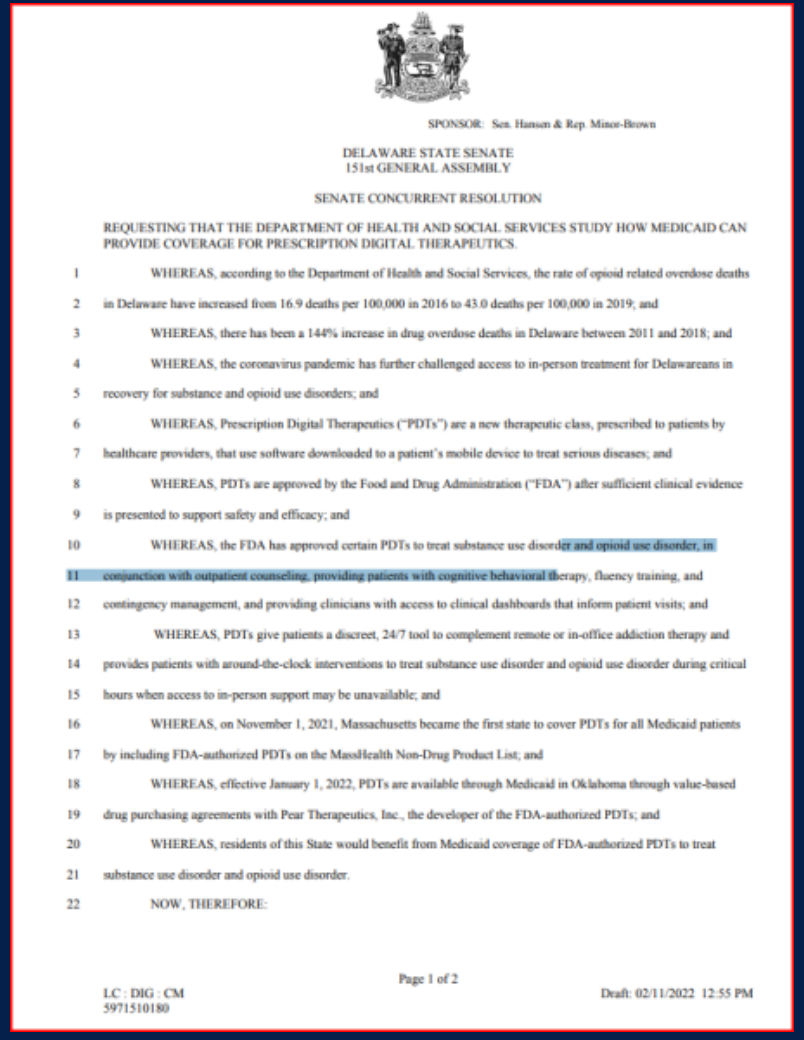
"A9291 - HCPCS Code for Pres Dig Cog Behav Thera Fda." *Hcpcs.codes*, hcpcs.codes/a-codes/A9291/

Reimbursement

- The only public coverage for prescription DHT is through individual contracts with state Medicaid plans
  - Massachusetts: reSET and reSET-O are covered for MassHealth members without prior authorization or copayment
    - Pear Therapeutics is located in Boston
  - Oklahoma: entered a value-based agreement with Pear Therapeutics and made reSET and reSET-O available to beneficiaries enrolled in the Oklahoma Health Care Authority (OHCA) SoonerCare program.
    - OHCA did not disclose the specific performance and outcomes-based benchmarks being monitored under the agreement
- State and commercial payers remain hesitant to provide coverage due to concerns about generalizability, the lack of long-term studies to evaluate efficacy and benefit and the lack of data regarding cost-effectiveness when compared to standard treatment.

Patel, Nisarg. "Medicare Billing Codes for Digital Therapeutics: A Path Forward." *Health Affairs Forefront*, 22 Aug. 2022, www.healthaffairs.org/content/forefront/medicare-billing-codes-digital-therapeutics-path-forward,

Legislative Efforts



SPONSOR: Sen. Hansen & Rep. Minor-Brown

DELAWARE STATE SENATE
151st GENERAL ASSEMBLY

SENATE CONCURRENT RESOLUTION

REQUESTING THAT THE DEPARTMENT OF HEALTH AND SOCIAL SERVICES STUDY HOW MEDICAID CAN PROVIDE COVERAGE FOR PRESCRIPTION DIGITAL THERAPEUTICS.

WHEREAS, according to the Department of Health and Social Services, the rate of opioid related overdose deaths in Delaware have increased from 16.9 deaths per 100,000 in 2016 to 43.0 deaths per 100,000 in 2019; and

WHEREAS, there has been a 144% increase in drug overdose deaths in Delaware between 2011 and 2018; and

WHEREAS, the coronavirus pandemic has further challenged access to in-person treatment for Delawareans in recovery for substance and opioid use disorders; and

WHEREAS, Prescription Digital Therapeutics ("PDTs") are a new therapeutic class, prescribed to patients by healthcare providers, that use software downloaded to a patient's mobile device to treat serious diseases; and

WHEREAS, PDTs are approved by the Food and Drug Administration ("FDA") after sufficient clinical evidence is presented to support safety and efficacy; and

WHEREAS, the FDA has approved certain PDTs to treat substance use disorder and opioid use disorder, in conjunction with outpatient counseling, providing patients with cognitive behavioral therapy, fluency training, and contingency management, and providing clinicians with access to clinical dashboards that inform patient visits; and

WHEREAS, PDTs give patients a discreet, 24/7 tool to complement remote or in-office addiction therapy and provides patients with around-the-clock interventions to treat substance use disorder and opioid use disorder during critical hours when access to in-person support may be unavailable; and

WHEREAS, on November 1, 2021, Massachusetts became the first state to cover PDTs for all Medicaid patients by including FDA-authorized PDTs on the MassHealth Non-Drug Product List; and

WHEREAS, effective January 1, 2022, PDTs are available through Medicaid in Oklahoma through value-based drug purchasing agreements with Pear Therapeutics, Inc., the developer of the FDA-authorized PDTs; and

WHEREAS, residents of this State would benefit from Medicaid coverage of FDA-authorized PDTs to treat substance use disorder and opioid use disorder.

NOW, THEREFORE:

LC : DIG : CM
5971510180

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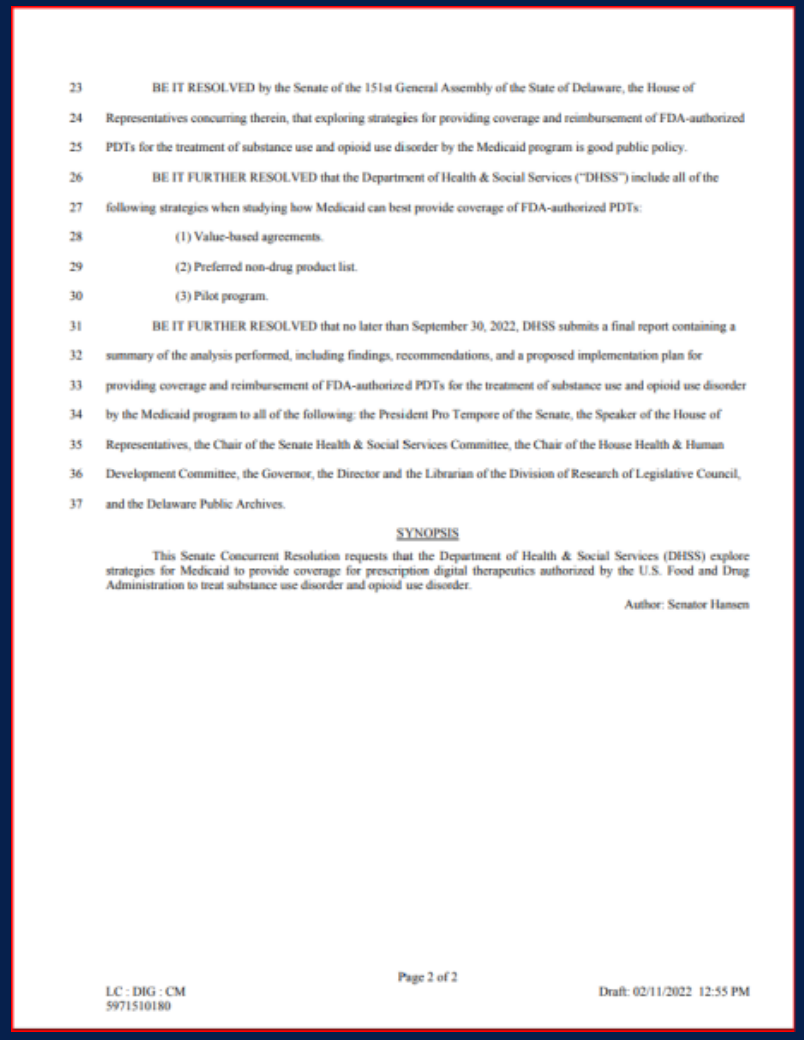


BE IT RESOLVED by the Senate of the 151st General Assembly of the State of Delaware, the House of Representatives concurring therein, that exploring strategies for providing coverage and reimbursement of FDA-authorized PDTs for the treatment of substance use and opioid use disorder by the Medicaid program is good public policy.

BE IT FURTHER RESOLVED that the Department of Health & Social Services ("DHSS") include all of the following strategies when studying how Medicaid can best provide coverage of FDA-authorized PDTs:

(1) Value-based agreements.

(2) Preferred non-drug product list.

(3) Pilot program.

BE IT FURTHER RESOLVED that no later than September 30, 2022, DHSS submits a final report containing a summary of the analysis performed, including findings, recommendations, and a proposed implementation plan for providing coverage and reimbursement of FDA-authorized PDTs for the treatment of substance use and opioid use disorder by the Medicaid program to all of the following: the President Pro Tempore of the Senate, the Speaker of the House of Representatives, the Chair of the Senate Health & Social Services Committee, the Chair of the House Health & Human Development Committee, the Governor, the Director and the Librarian of the Division of Research of Legislative Council, and the Delaware Public Archives.

SYNOPSIS

This Senate Concurrent Resolution requests that the Department of Health & Social Services (DHSS) explore strategies for Medicaid to provide coverage for prescription digital therapeutics authorized by the U.S. Food and Drug Administration to treat substance use disorder and opioid use disorder.

Author: Senator Hansen

LC : DIG : CM
5971510180

Draft: 02/11/2022 12:55 PM

Legislative Efforts

- 117th Congress
  - Senate Bill 3791/ House Bill 7051
    - Access to Prescription Digital Therapeutics Act of 2022 (March 2022)
  - Senate Bill 5238
    - Medicaid and CHIP Access to Prescription Digital Therapeutics Act (December 2022)
  - Lack of common standards for regulatory clearance and for how to generate the evidence necessary to support medical claims and develop standards for clinical implementation and best practices make it crucial that legislative mandates do not outpace what is known about the efficacy and safety of these interventions

www.congress.gov

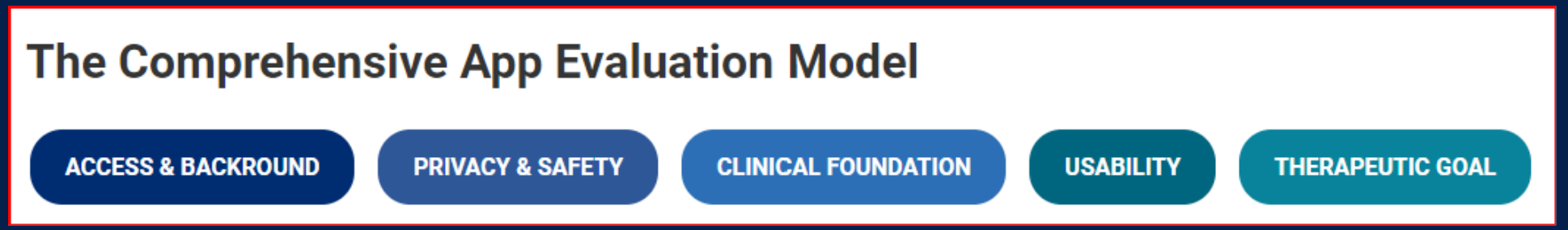
Evaluating and Incorporating DHT

1. https://policysearch.ama-assn.org/policyfinder/detail/mobile%20health?uri=%2FAMADoc%2FHOD-480.943..xml

Evaluating and Incorporating DHT

APP ADVISOR
An American Psychiatric Association Initiative

“The purpose of the evaluation is to give the psychiatrist and the patient sufficient information from which to make an informed decision that they deem correct for their situation.”



https://www.psychiatry.org/psychiatrists/practice/mental-health-apps/the-app-evaluation-model

Evaluating and Incorporating DHT

Evaluation Model Screener

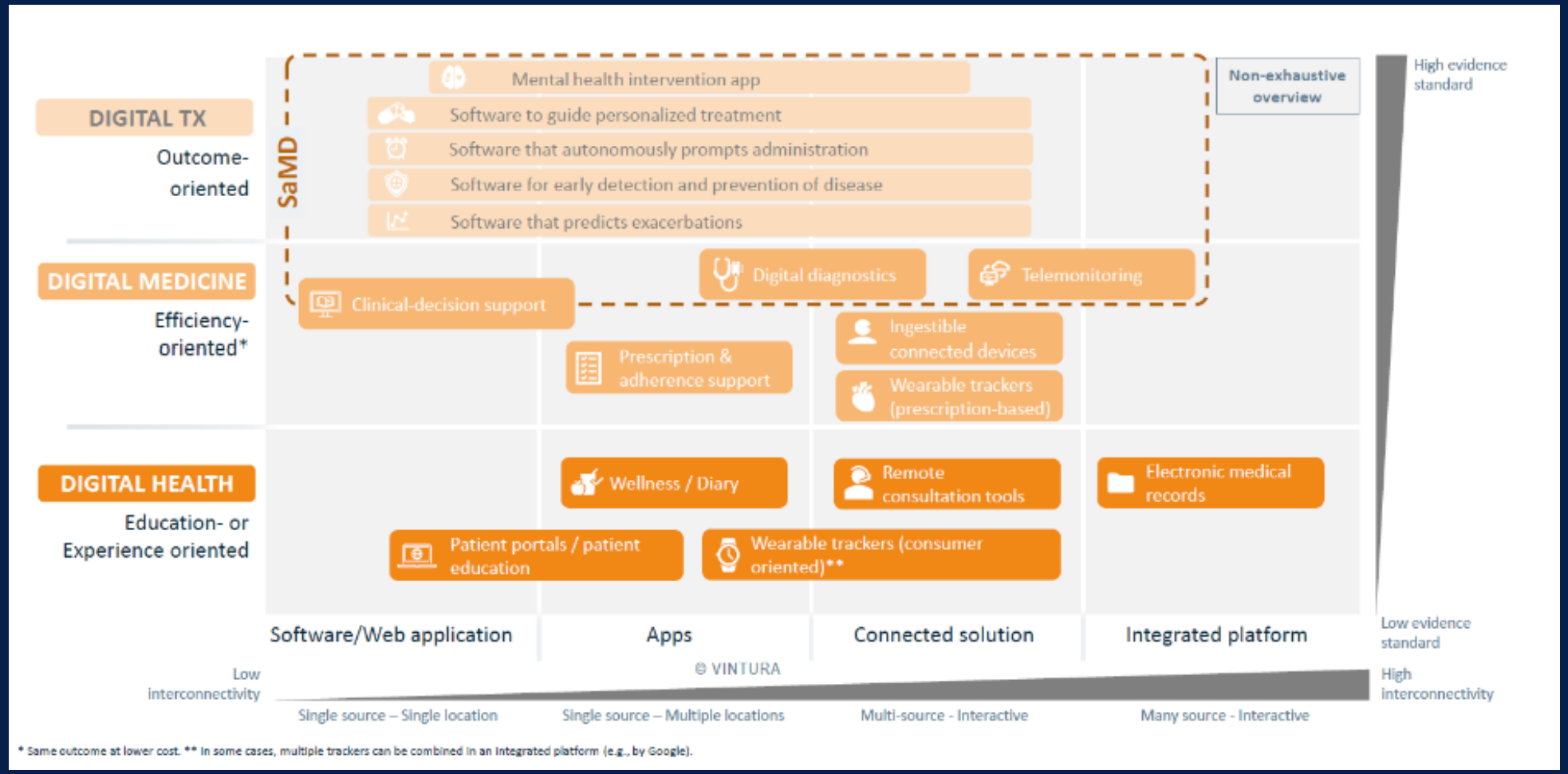
APP ADVISOR
An American Psychiatric Association Initiative

The below Model is comprehensive. This brief version of the Model extracts a sample of the most fundamental questions that should be asked before considering using an app, and can serve as a good "jumping off" point to get you started:

1. On which platforms/operating systems does the app work? Does it also work on a desktop computer?
2. Has the app been updated in the last 180 days?
3. Is there a transparent privacy policy that is clear and accessible before use?
4. Does the app collect, us, and/or transmit sensitive data? If yes, does it claim to do so securely?
5. Is there evidence of specific benefit from academic institutions, end user feedback, or research studies?
6. Does the app have a clinical/recovery foundation relevant to your intended use?
7. Does the app seem easy to use?
8. Can data be easily shared and interpreted in a way that's consistent with the stated purpose of the app?

https://www.psychiatry.org/psychiatrists/practice/mental-health-apps/the-app-evaluation-model

Digital Health Continuum



https://www.vintura.com/news/explaining-the-diversity-of-digital-health-solutions/

Final Takeaways/Summary (Suggested)

- Digital Health, Medicine and Therapeutics have the potential to improve population health, patient and clinician experience, clinical outcomes and health disparities
- However, without more rigorous and independent research, evidenced based, standardized workflows for implementation and on-going prescribing, concrete legal and regulatory guidance regarding privacy, a focus on healthcare equity and fair reimbursement models, this potential may never be fully realized.

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