

# Realizing the Promise of Prescription Digital Therapeutics



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#NatAllForum

# Prescription Digital Therapeutic Learning Collaborative

- Purpose:
  - Build an understanding of the impact of PDTs,
  - Provide resources and strategies that can assist employers in developing successful benefit design approaches to utilize PDTs in 2024 - 2025
- Timeframe: 6 months
- Participants: 4 Coalitions and 15 Employers
  - Marianne Fazen, Dallas Fort-Worth Business Group on Health
  - Jenny Goins, Kentuckiana HealthCARE Collaborative
  - Dawn Weddle, Midwest Business Group on Health
  - Jon Rankin, North Carolina Business Coalition on Health



## Benefits of Digital Health

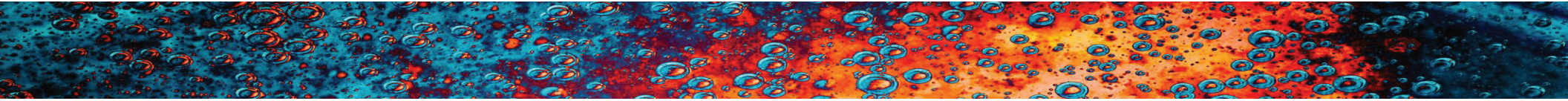
- Patient Engagement
- Health Deserts
- Lack of Health Specialists
- Scaling Chronic Disease Management
- Overcoming Logistical Barriers to Care
- Data Interoperability
- Medical Cost Control
- Employee Recruitment and Retention

There are over 300,000 health related apps on the market.

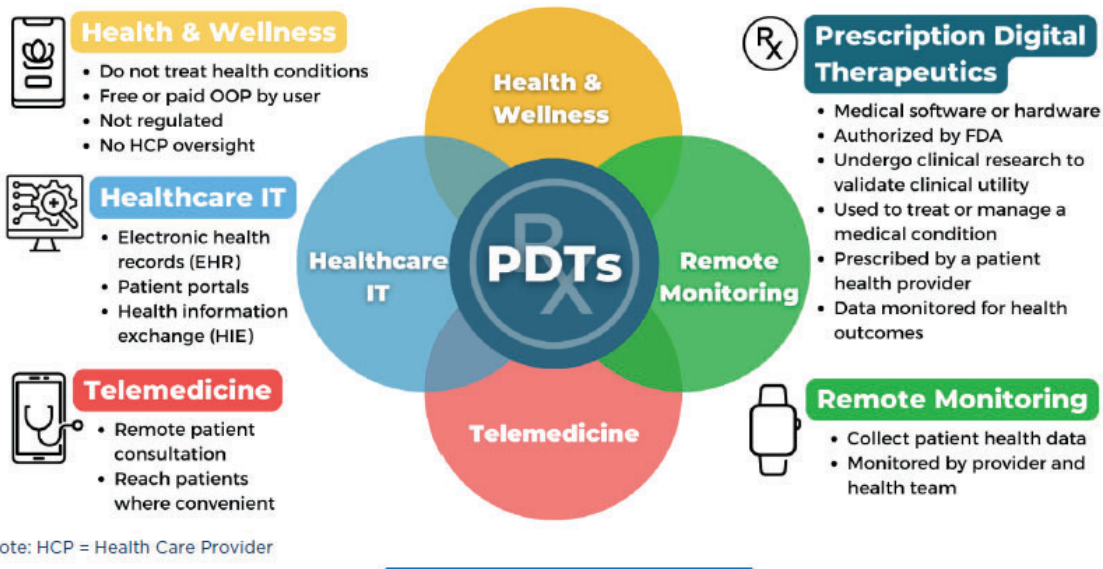


Less than <1% are evaluated by the FDA.

<https://www.iqvia.com/insights/the-iqvia-institute/reports/the-growing-value-of-digital-health>



## WHERE DO PDTS FIT INTO HEALTHCARE?



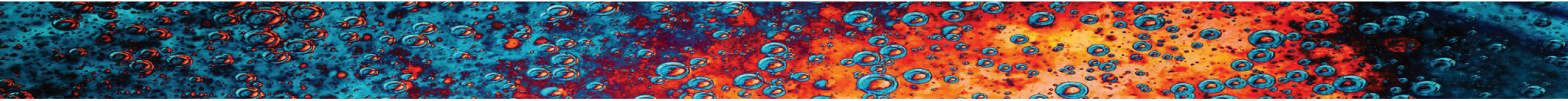
- FDA authorized
- Held to regulatory standards for medical devices, including privacy and data management
- Developed in accordance with good manufacturing practices like medications
- Undergo clinical research to demonstrate efficacy through clinical trials
- Require a prescription and oversight from a healthcare professional
- Used to treat or manage a condition

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# Otsuka Has a Vast, Global Footprint

We have a network of 180 companies and more than 47,000 employees<sup>1</sup>

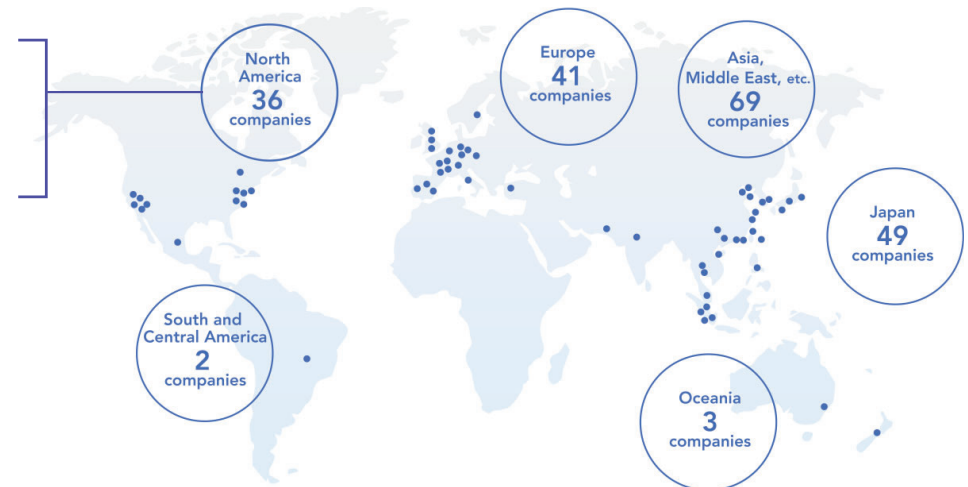
OTSUKA PHARMACEUTICAL DEVELOPMENT & COMMERCIALIZATION, INC. (OPDC)<sup>2</sup>  
Develops promising drug candidates from clinical-trial management through planning the strategy for drug approval, marketing, and life-cycle management  
**Corporate offices: Rockville, MD** – Established in 1989    **Hayward, CA** – Established in 2020

OTSUKA AMERICA PHARMACEUTICAL, INC. (OAPI)<sup>2</sup>  
Oversees commercial activities in the United States with a diverse and comprehensive product offering  
**Corporate offices: Princeton, NJ** – Established in 2007

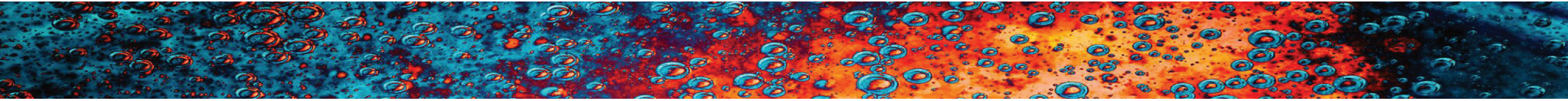
## Pharmaceuticals

- Neuroscience<sup>3</sup>
- Nephrology
- Gastrointestinal
- Clinical Nutrition
- Diagnostics
- Digital Therapeutics**
- Medical Devices

9 of the North American companies manage our pharmaceutical business



**References:** 1. Otsuka America Pharmaceutical, Inc., earns designation as a Great Place to work-certified™ company in 2020. Otsuka America Pharmaceutical, Inc., earns designation as a Great Place to Work-Certified™ Company In 2020 | Discover Otsuka. Accessed June 7, 2022. [https://www.otsuka-us.com/discover/otsuka-earns-designation-as-a-great-place-to-work#:~:text=\(OPDC\)%20and%20Otsuka%20America%20Pharmaceutical,to%20address%20unmet%20healthcare%20needs](https://www.otsuka-us.com/discover/otsuka-earns-designation-as-a-great-place-to-work#:~:text=(OPDC)%20and%20Otsuka%20America%20Pharmaceutical,to%20address%20unmet%20healthcare%20needs) 2. Otsuka Corporate Value Proposition. 3. Pharmaceuticals. Otsuka Holdings Co., Ltd. Accessed March 2, 2022. <https://www.otsuka.com/en/rd/business/pharmaceuticals/>



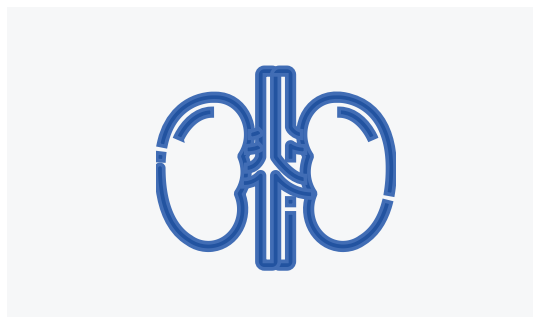
# Leading by Example, We're Focused on Changing the Face of Healthcare

We are doing everything we can to live up to our mission in 3 critical categories.



## NEUROSCIENCE

Our driving philosophy at Otsuka is to serve those with unmet medical needs, and it's why **we're dedicated** to the central nervous system (CNS) space



## NEPHROLOGY

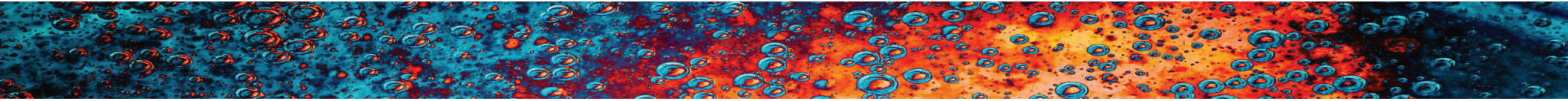
When Otsuka saw a need for clinical expertise and research in the nephrology space, **we led the way**



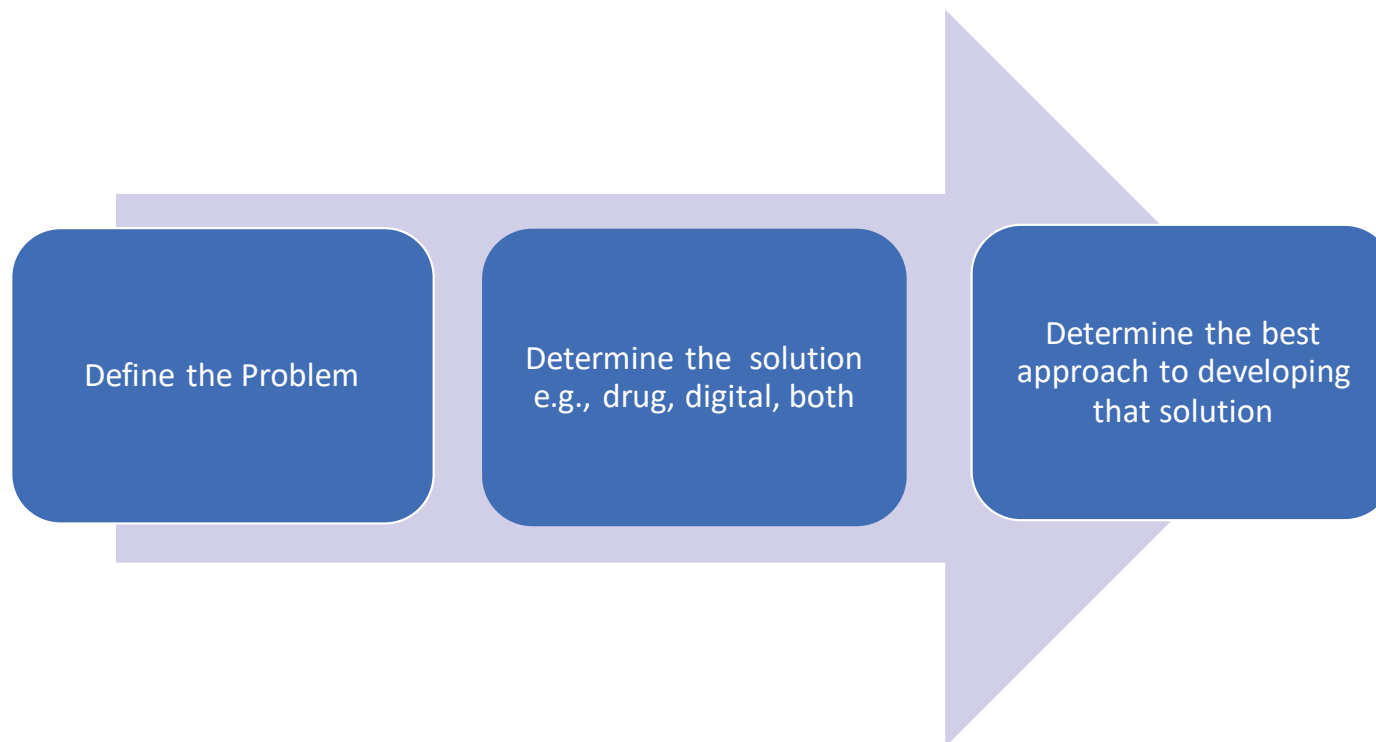
## DIGITAL INNOVATION

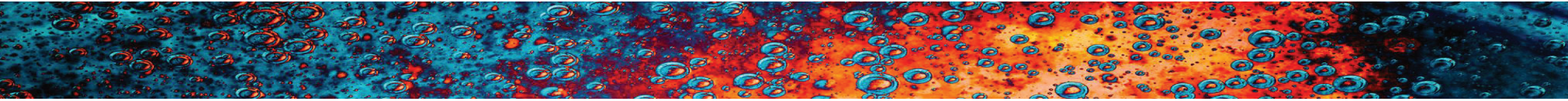
Digital technology has not only changed the world we live in, it's why we're **changing the face of healthcare**





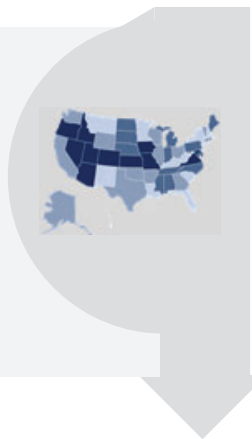
## The approach to finding solutions for unmet medical needs





# Digital therapeutics and solutions may have the potential to help equalize access to mental health care and to address disparities in the current health care system

**Patients often do not receive treatment**  
More than half of patients with a mental illness do not receive treatment, totaling over 27 million adults<sup>1</sup>



**Even when patients do receive treatment, a large proportion have a suboptimal response**  
As evidenced in STAR\*D<sup>2</sup>, CATIE<sup>3</sup>, STEP-BD<sup>4</sup>, CO-MED<sup>5</sup>, VAST-D<sup>6</sup>



Digital therapeutics may help bridge this gap by expanding access to mental health care when paired with commonly used treatment methods

1. Mental Health America, *The State of Mental Health in America, 2022 Findings*. 2. Unützer and Park, *Strategies to improve the management of depression in primary care*, *Prim Care*, 2012. 3. American Psychiatric Association, *Practice Guideline for the Treatment of Patients With Major Depressive Disorder*, American Psychiatric Association 2010; 4. Avalore Health and Mental Health America, *Shortening the Road to Recovery: Barriers and Opportunities to Improve Quality of Care for Major Depressive Disorder*; 5. Mohr, et al., *Behavioral Intervention Technologies: Evidence Review And Recommendations For Future Research In Mental Health*, *Gen Hosp Psychiatry*, 2013. 6. Knickman, et al. *Improving Access to Effective Care for People Who Have Mental Health and Substance Use Disorders - A Vital Direction for Health and Health Care*

# Key considerations for a methodologically robust DTx clinical trial design



## Study Protocol

- **Robust comparator arm selection**
- **Blinding** considerations due to visible app content
- **Novel and relevant measurement**, e.g. app adherence, satisfaction scales
- **Medical device AE reporting**



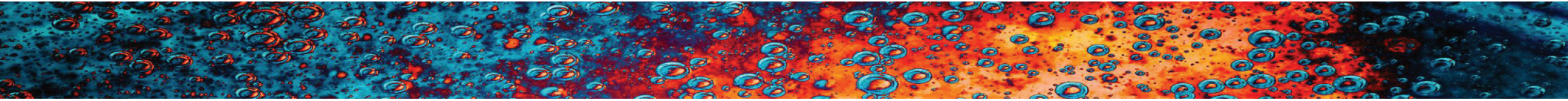
## Study Protocol

- **Randomization processes** for an app
- **Site training** for an app study
- **Study documentation templates**



## Study execution

- Subject **“onboarding”** for an app (vs pill)
- **Technical support services**
- **App adherence tracking**



# Digital solutions have different levels of regulatory oversight

## DIGITAL THERAPEUTICS (DTx)

	DIGITAL HEALTH AND WELLNESS	DIGITAL MEDICINE	NONPRESCRIPTION DIGITAL THERAPEUTICS (DTx)	PRESCRIPTION DIGITAL THERAPEUTICS (PDTs)
TECHNOLOGY ROLE IN CARE	Nonregulated solutions designed to coach, educate, and provide feedback to help people lead healthier lives and avoid stress-related illness	Technology informs and facilitates treatment	Software that delivers <b>disease-specific treatment</b> ; may be marketed under FDA enforcement discretion policy with limited clinically validated safety and efficacy	<b>FDA-authorized SaMD</b> , evaluated and clinically validated for safety and efficacy. Delivers disease-specific, evidence-based treatment. <b>By Rx only</b>
ROLE OF CLINICIAN(S)	Varies by application	Actively involved	May be involved	Actively involved
REGULATORY OVERSIGHT	<b>Not subject to FDA review</b>	<b>Type of FDA review and authorization varies by product type</b>	<b>May be subject to FDA review</b>	<b>FDA-authorized SaMD; evaluated and clinically validated for safety and efficacy</b>
CLINICAL EVIDENCE	Typically, not required	Required	Limited; may not be required	Required, with demonstrated patient outcomes
INSURANCE BENEFIT DESIGN CONSIDERATIONS	Out-of-pocket payment and/or EAPs	Dependent on solution type, coverage reduces access barriers	Out-of-pocket payment and/or EAPs	Coverage is rapidly evolving and essential to reducing access barriers. May be covered under medical or pharmacy benefit, depending on solution. Covered upon employer request by prominent PBM organizations

# Realizing the Promise of Prescription Digital Therapeutics



**Dawn Weddle,**  
Vice President, Midwest Business Group on Health

#NatAllForum

# Midwest Business Group on Health: Our Journey to Better Understand the PDT Space

## Employer Value Proposition

1. Provides clinician with patient reported outcomes
2. Enhances ability for patients to track their needs/health status throughout the day
3. Provides 24/7 access to care through remote care and monitoring
4. Lowers the risk of side effects (compared with prescription drugs)

- Employer Advisory Board
- Published Action Brief
- Conducted Employer Workshop

**EMPLOYER ACTION BRIEF**

**MBGH**  
Midwest Business Group on Health

**New Frontiers in Digital Health: Prescription Digital Therapeutics**

**FDA Authorization Process for PDTs**

**Prescription Digital Therapeutics**

**Remote Patient Monitoring**

**Digital Therapeutics**

**Health & Wellness Apps**

**Prescription**

Remote Patient Monitoring	Digital Therapeutics	Health & Wellness Apps	Prescription
<ul style="list-style-type: none"> <li>Remote Patient Monitoring (RPM)</li> <li>Chronic health data</li> <li>Track and analyze health data</li> <li>Remote patient monitoring</li> <li>Remote health services</li> <li>Support for chronic conditions</li> </ul>	<ul style="list-style-type: none"> <li>Digital Therapeutics (DTx)</li> <li>Chronic health services (CHS)</li> <li>Health information exchange (HIE)</li> <li>Virtual care</li> </ul>	<ul style="list-style-type: none"> <li>Health &amp; Wellness Apps</li> <li>Virtual care services</li> <li>Virtual patient care</li> </ul>	<ul style="list-style-type: none"> <li>Prescription</li> <li>Virtual care services</li> <li>Virtual patient care</li> <li>Virtual care services</li> <li>Virtual patient care</li> </ul>

**Midwest Business Group on Health**  
Catalysts for *Change* in Health Care & Benefits



## PDT Learning Collaborative: Employer Recommendations

- Do your own research to gain a better understanding of the...
  - Difference between digital apps, digital therapies and PDTs
  - Total cost of care for PDT disorders/conditions
  - Role of PDTs to fill gaps in care – mental health, shift workers and rural employees
- Put your consultant, PBM and health plan on notice – they are responsible for bringing solutions to YOU and YOUR MEMBERS!
  - Get the full story - incentives, mark-ups, contracted rates, formulary tier, rebates
  - Ask about roadblocks
  - Discuss strategy for communicating availability of PDTs
- Consider pilot
  - Evaluate engagement, communication needs and outcomes



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**Pamela Hannon**

Retirement and Healthcare Leader,  
GE Healthcare

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# GE HealthCare

A leading global medtech, pharmaceutical diagnostics, and digital solutions innovator

\$18.3B Revenue in 2021

50K Employees worldwide

160+ Countries

1B+ Patients served annually

## Business segments

- Imaging
- Ultrasound
- Patient Care Solutions (PCS)
- Pharmaceutical Diagnostic (PDx)

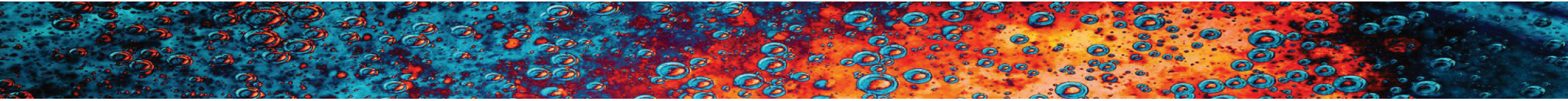


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**Marianne Fazen, PhD**  
Executive Director,  
Dallas Fort Worth Business Group on Health

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## DFWBGH Employers' Key Takeaways from PDT Learning Collaborative

- PDTs are still too new to employer market and relatively unknown to employers, physicians, plans & patients, despite advantages of reduced cost, easier access, increased adherence, improved treatment oversight, etc.
- Digital products are already very popular, so less resistance to PDTs is likely
- Benefits Managers have limited time & bandwidth to investigate, promote, or manage PDTs
- Key challenges to adding/expanding PDT coverage for employees
  - Available for limited set of conditions
  - Confusion about Medical or PBM coverage
  - Expect difficulties in obtaining & evaluating PDT utilization data, reimbursement & accountability
  - Extra education/communications needed for employee & physician adoption
- Employer PDT Action Plans
  - Ask/investigate PBM & carriers about PDT coverage & physician prescribers
  - Obtain PDT data to evaluate PDT performance and cost savings
  - Develop communication & referral plan to ensure targeted members can enroll & engage in PDT solution



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HR Vendor Management, Budget, Contracts Administrator,  
City of Dallas

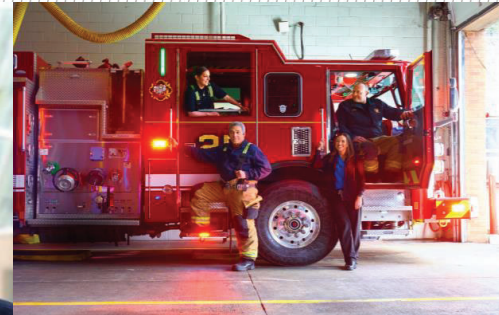


**City of Dallas**

# Realizing the Promise of Prescription Digital Therapeutics (PDTs)

November 2023

Cheryl Mayo, M.S.P.H,  
Administrator  
Human Resources Strategic  
Employment Initiatives,  
Budget and Contracts



12,772 Employees  
4,076 Retirees  
Over 23,000 covered lives





# Advancing Well-being

<h2>Social</h2>  <p>Promoting and sustaining supportive, positive relationships.</p>	<h2>Financial</h2>  <p>Access to resources that support managing economic life and security.</p>	<h2>Physical</h2>  <p>Good health and energy to perform daily life tasks.</p>	<h2>Community</h2>  <p>Liking where one lives, feeling safe, and giving back.</p>	<h2>Mental</h2>  <p>Ability to endure daily stress and strengthen resiliency.</p>
<ul style="list-style-type: none"><li>✓ Hiring Events</li><li>✓ Diversity Dashboard</li><li>✓ Upskilling Workforce</li><li>✓ Virtual/On-site Health Expos</li></ul>	<ul style="list-style-type: none"><li>✓ \$2,000 Childcare subsidy</li><li>✓ Retiree Comeback Provision</li><li>✓ Pet Insurance</li><li>✓ Free Diabetic/HBP Medications</li></ul>	<ul style="list-style-type: none"><li>✓ Biometric screenings</li><li>✓ Simplified Incentive Program</li><li>✓ Wellness Challenges</li><li>✓ Diabetes Hypertension Program</li></ul>	<ul style="list-style-type: none"><li>✓ Dallas Heart Walk</li><li>✓ Hybrid Work Opportunity</li><li>✓ Employee Cares Committee</li></ul>	<ul style="list-style-type: none"><li>✓ COVID-19 Support</li><li>✓ Mental health leave</li><li>✓ 6 weeks paid parental leave</li></ul>



# Highly Digital Health Strategy - 2023



## Data and outcomes

Continue evaluating performance and ROI

Identify additional targeted programs to reduce cost

## Healthcare delivery through technology

Telehealth

Mobile health

Video Conferencing

Remote Patient Monitoring (RPM)

## Benefits needs of contingent work employee

Explore & Evaluate Part-Time Employee Benefits

Coordination of benefits for returning retirees

Establishment of PEO

## Personalized and easy to use benefits

Explore better ways to communicate with the multiple generations of employees

Continue to evaluate utilization

Increased Family Support Programs





# Contact Us

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Thank you!



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