



# PARTNERSHIP FORUM

No.2 = 2021

Digital Therapeutics:  
The Evolving Role of Digital Therapeutics

AUG. 31-SEP. 1, 2021



# Moderator Welcome



Drake Reiter, PharmD  
Executive Fellow in Health Care Association Leadership

## Disclaimer

Organizations may not re-use material presented at this AMCP webinar for commercial purposes without the written consent of the presenter, the person or organization holding copyright to the material (if applicable), and AMCP. Commercial purposes include but are not limited to symposia, educational programs, and other forms of presentation, whether developed or offered by for-profit or not-for-profit entities, and that involve funding from for-profit firms or a registration fee that is other than nominal. In addition, organizations may not widely redistribute or re-use this webinar material without the written consent of the presenter, the person or organization holding copyright to the material (if applicable), and AMCP. This includes large quantity redistribution of the material or storage of the material on electronic systems for other than personal use.

# AMCP Partnership Forums

## Collaboration for Optimization



AMCP Partnership Forums bring key decision makers in managed care, integrated care, the pharmaceutical industry, and others together to discuss and collaborate on tactics and strategies to drive efficiencies and outcomes in integrated care and managed care.



# Partnership Forums

- Provide a voice for stakeholders
- Find common ground and gain consensus
- Identify actionable results
- Amplify to raise visibility

# Goals of this Partnership Forum

- Identify current marketplace challenges and areas of opportunity around the coverage and use of digital therapeutics (DTx)
- Provide input on a set of draft definitions and guiding principles intended to:
  - Help digital therapeutic innovators understand standards of evidence expected to accompany DTx
  - Assist health care decision makers in making coverage decisions for DTx
  - Improve understanding of DTx benefits, risks and value thereby improving appropriate patient access

# Thank You to Our Sponsors

---

HOSTED BY AMCP IN PARTNERSHIP WITH

---



AKILI



PEAR  
THERAPEUTICS



Pfizer



PhRMA  
RESEARCH • PROGRESS • HOPE

**SIMON ♦ KUCHER & PARTNERS**  
Strategy & Marketing Consultants



Takeda



theranica



Woebot<sup>®</sup>  
Health

# Our Faculty



Jamie Van Iderstine  
Senior Vice President, Client  
Engagement  
Cyan Health



Theresa Juday, RPh  
Director, Specialty Product  
Development  
CVS Health



Danielle Massie, PharmD  
Pharmacy Manager, Business  
Development  
Moda Health



# Agenda

- Key background
- Pre-forum stakeholder perspectives on DTx
- Forum findings
  - Challenges & considerations for DTx
  - Opportunities & guidance for stakeholders
- Q&A
- What's next?





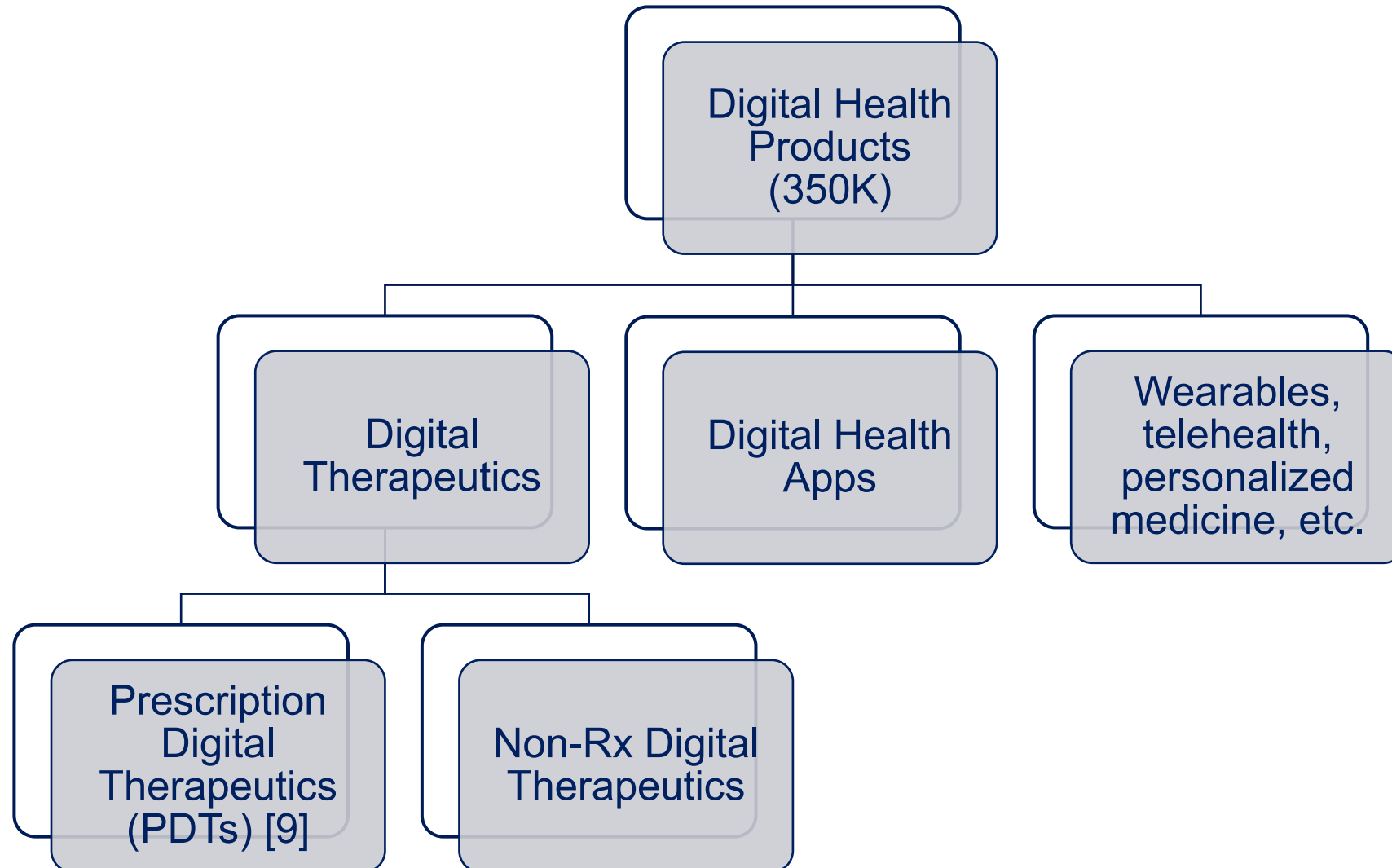
# Key Background



# What are DTx?

- “Products designed to stand alone or work in combination with existing medications or treatments, **helping patients prevent, treat, and/or manage their disease while ensuring optimal health outcomes** from therapy. A key distinguishing feature of a prescription (or regulated) DTx product is that it **makes a health claim that is validated by a third party** (e.g., a regulatory authority).” - AMCP
- “Deliver evidence-based therapeutic interventions that are driven by high quality software programs to **prevent, manage, or treat a medical disorder or disease**. Used independently or in concert with medications, devices, or other therapies to **optimize patient care and health outcomes**.” - DTA

# DTx ≠ Digital Health

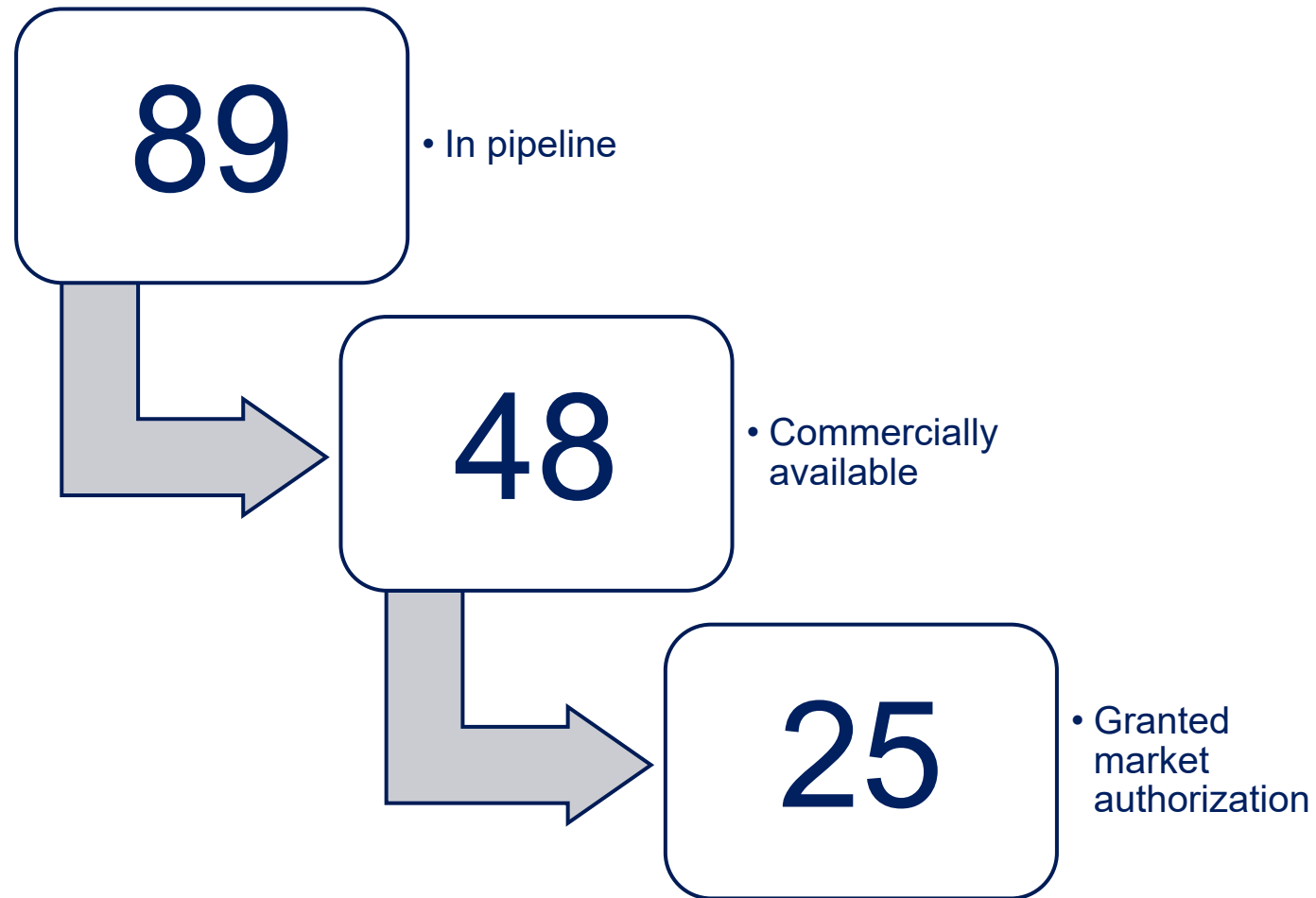


# Key Differences Between DTx & Digital Health Apps

Digital Therapeutics	Digital Health Apps
Regulated	Unregulated
May make efficacy claim	No efficacy claim
*Three pathways for market authorization: <ul style="list-style-type: none"><li>• 510(k)</li><li>• De Novo Classification</li><li>• Precertification (Pre-Cert)</li></ul>	No pathway for market authorization

\*Pre-Cert program still in pilot phase

# DTx Acceleration



<https://www.iqvia.com/insights/the-iqvia-institute/reports/digital-health-trends-2021>

# Additional Resources on DTx



- AMCP Partnership Forum: Digital Therapeutics—What Are They and Where Do They Fit in Pharmacy and Medical Benefits? J Manag Care Spec Pharm volume 25, Issue number: 5 (2020). Available online at: <https://www.jmcp.org/doi/10.18553/jmcp.2020.19418>
- Benjamin Parcher & Megan Coder. Decision makers need an approach to determine digital therapeutic product quality, access, and appropriate use. J Manag Care Spec Pharm volume 27, Issue number: 4 (2021). Available online at: <https://www.jmcp.org/doi/full/10.18553/jmcp.2021.27.4.536>
- Simon C. Mathews, Michael J. McShea, Casey L. Hanley, Alan Ravitz, Alain B. Labrique & Adam B. Cohen. Digital health: a path to validation. npj Digital Medicine volume 2, Article number: 38 (2019). Available online at: <https://www.nature.com/articles/s41746-019-0111-3#Sec1>
- Evidence Standards Framework for Digital Health Technologies NICE. March 2019. <https://www.nice.org.uk/Media/Default/About/what-we-do/our-programmes/evidence-standards-framework/digital-evidence-standards-framework.pdf>

# Understanding Stakeholder Perspectives on Digital Therapeutics

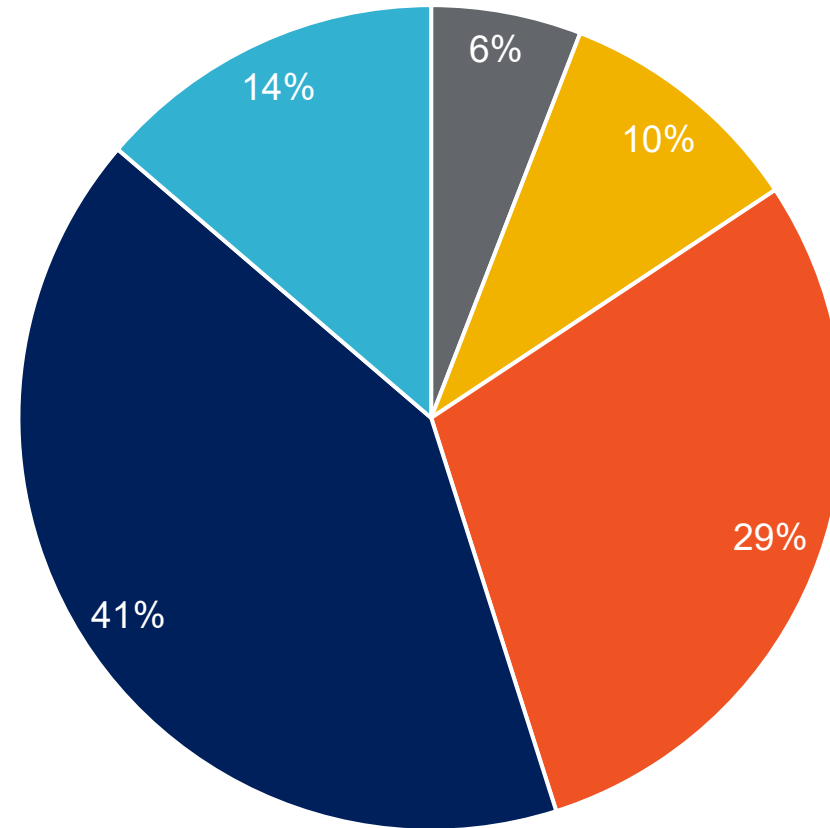




# An overwhelming majority of respondents indicated some acceleration of the adoption of DTx due to the pandemic

ALL RESPONDENTS

Rate at which the adoption of DTx is accelerating due to the pandemic (scale of 1-5)



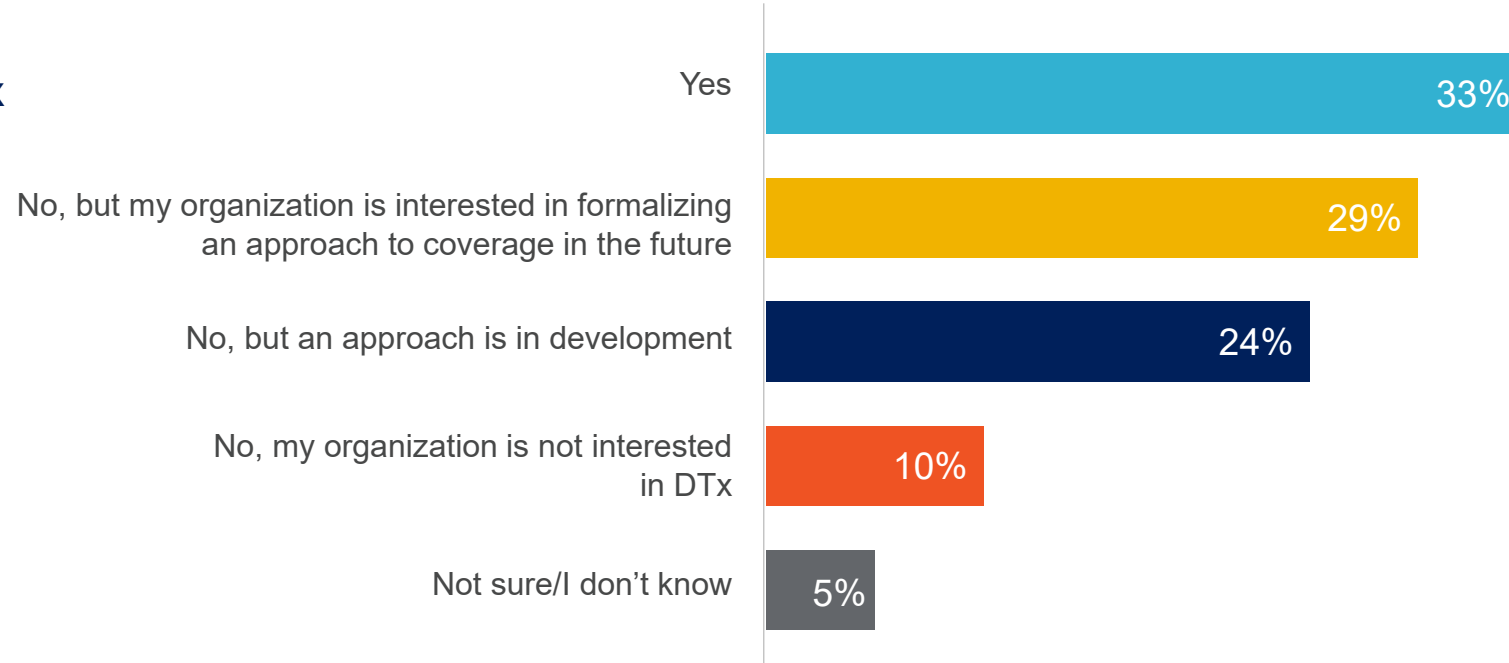
N=51 Respondents

# Payers appear to be moving toward more defined approaches to covering DTx



## PAYER RESPONDENTS

### % of payers with a defined approach for covering DTx



#### POINT OF INTEREST

**85% of payer respondents** either had a defined approach for covering DTx, or were planning to implement one

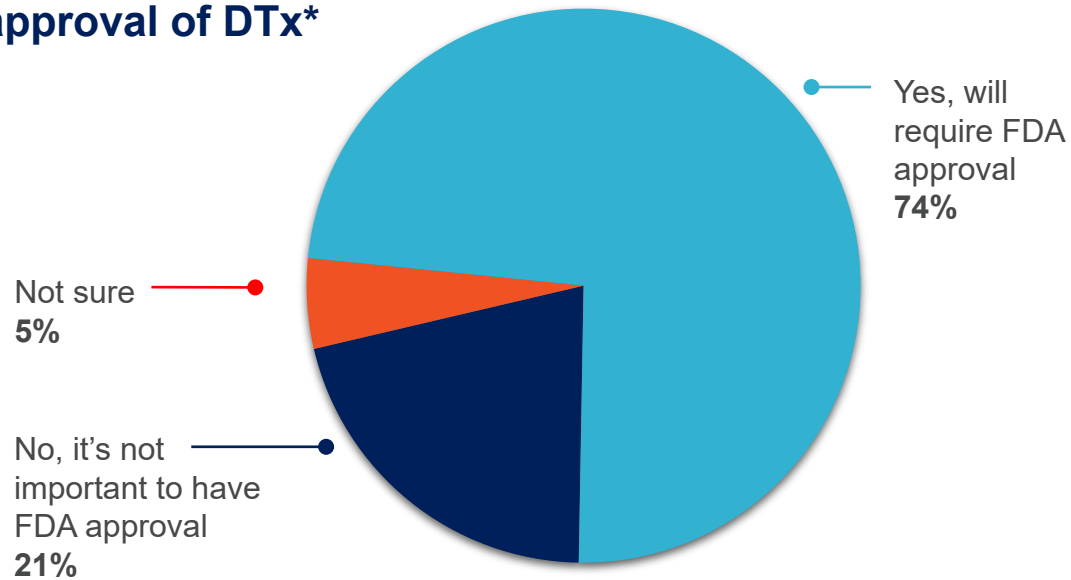
N=21 Payer Respondents  
DTx = digital therapeutics.

# Most payer respondents indicated a desire for meaningful evidence

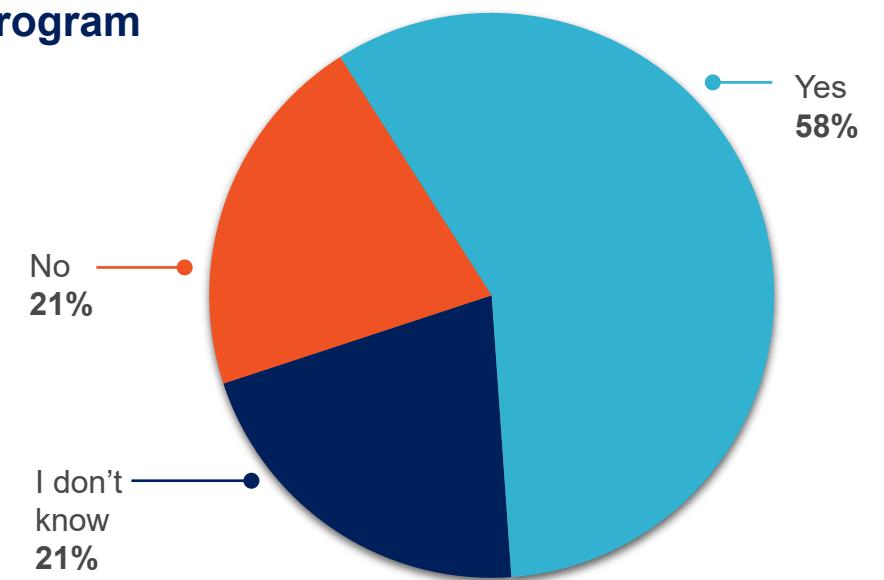


## PAYER RESPONDENTS

### Requirement for FDA approval of DTx\*



### Requirement for pilot program



#### POINT OF INTEREST

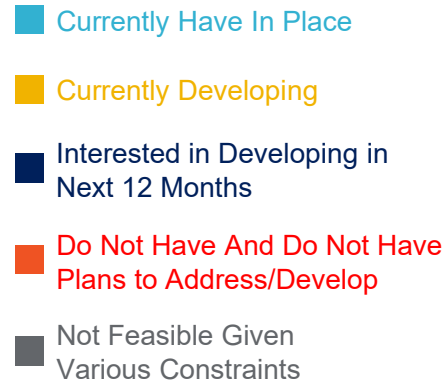
Payers indicated that **not all DTx** need to be FDA-approved to obtain coverage

N=19 Payer Respondents  
FDA = U.S. Food and Drug Administration.

# There is wide variation in payer organizational resources and capabilities related to the evaluation and implementation of DTx



## PAYER RESPONDENTS



Experience with or knowledge of DTx formulary dossier resources



Ability to interpret the data that has been collected and stored (data analysis)



Ability to create the infrastructure to store and query data (data engineering)



Ability to collect and ingest data (data integration)



N=21 Payer Respondents

# There is wide variation in payer organizational resources and capabilities related to the evaluation and implementation of DTx



## PAYER RESPONDENTS

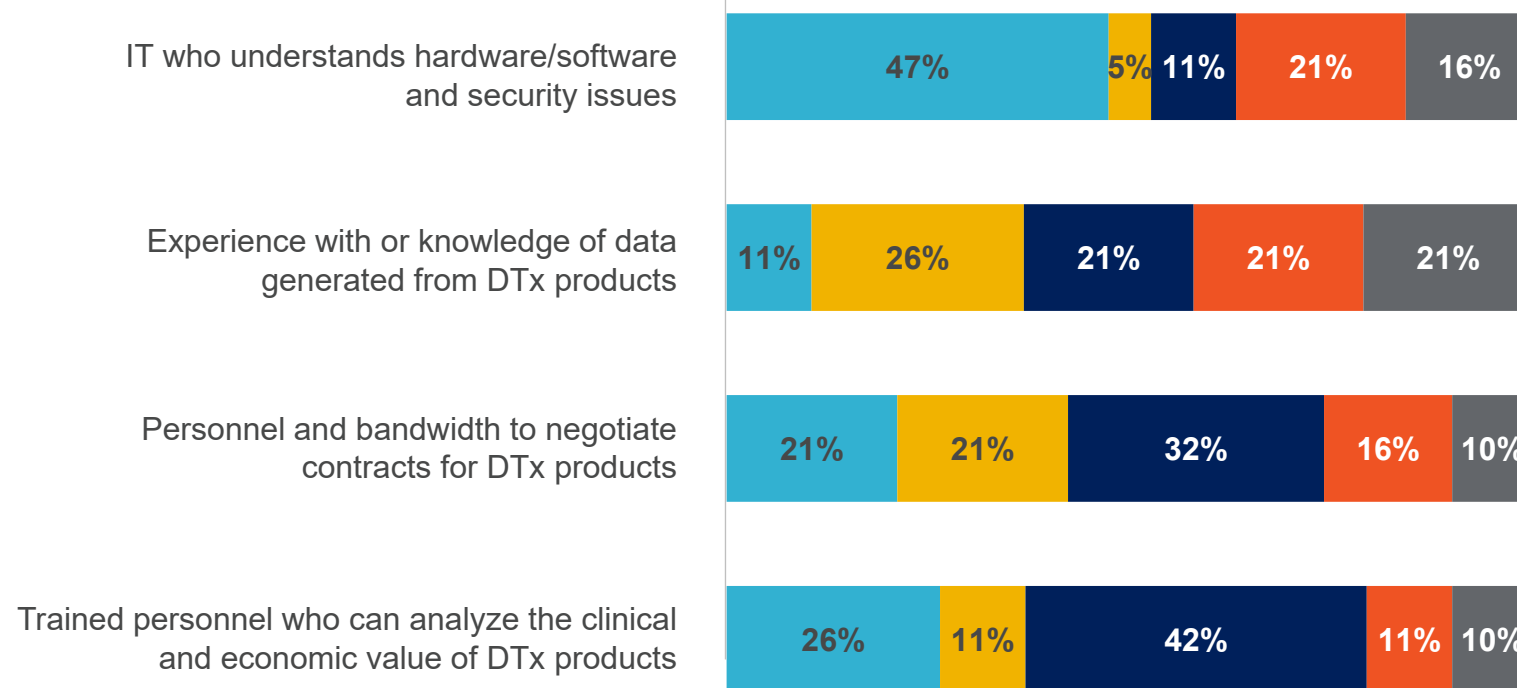
Currently Have In Place

Currently Developing

Interested in Developing in Next 12 Months

Do Not Have And Do Not Have Plans to Address/Develop

Not Feasible Given Various Constraints



### POINT OF INTEREST

**IT infrastructure and data analytics** appear to be the most widely developed capabilities

N=21 Payer Respondents

# Ambiguity of payer coverage appears to be the most significant hinderance to developing a DTx

## MANUFACTURER RESPONDENTS

### Degree to which various factors limit DTx development

■ Somewhat Limiting

■ Relatively Limiting

Limiting Factors	Ratings
The level of data/evidence you need to get coverage from a payer	■ Mean: 2.9 ± 0.74
Unclear opportunity for payer coverage	■ Mean: 2.8 ± 0.92
Perceived challenges with patient/caregiver uptake and engagement	■ Mean: 2.7 ± 0.94
Inability or unwillingness of leadership to enter into an agreement with payer partner that requires the level of trust and transparency necessary for DTx	■ Mean: 2.6 ± 1.64
Potential healthcare data compliance risks	■ Mean: 2.4 ± 0.83

Limiting Factors	Ratings
Development of data that shows durability of effect	■ Mean: 2.4 ± 0.96
Unclear or different regulatory pathways	■ Mean: 2.4 ± 0.96
Lack of physician willingness to prescribe and monitor	■ Mean: 2.3 ± 0.94
Inability to obtain accurate data/outcomes measures	■ Mean: 2.1 ± 0.99
Cost and logistics required to conduct clinical trials	■ Mean: 1.7 ± 0.82

N=9 Manufacturer Respondents

Scale: 1-Not at all limiting; 2-Relatively limiting; 3-Somewhat limiting; 4-Extremely limiting; 5-Does not apply.

## Survey Key Takeaways

- Payers appear to be moving toward **more defined approaches** to covering DTx
- **Meaningful evidence** will be necessary to support coverage
  - Including both **clinical trial** and **real-world** evidence (via pilot programs)
- There is **wide variation** in payer organizational **resources and capabilities** related to the evaluation and implementation of DTx
- For manufacturers, **ambiguity of payer coverage** appears to be the most significant hinderance to developing a DTx

The future of DTx promises many fruitful opportunities for cross-stakeholder collaboration—to align on shared priorities and bring innovative solutions to patients who need them.



# Challenges & Considerations for Digital Therapeutics



# Lack of Standardization

- System for categorization
- Benefit category for coverage
- **Evidence frameworks/expectations**
- Value assessment process

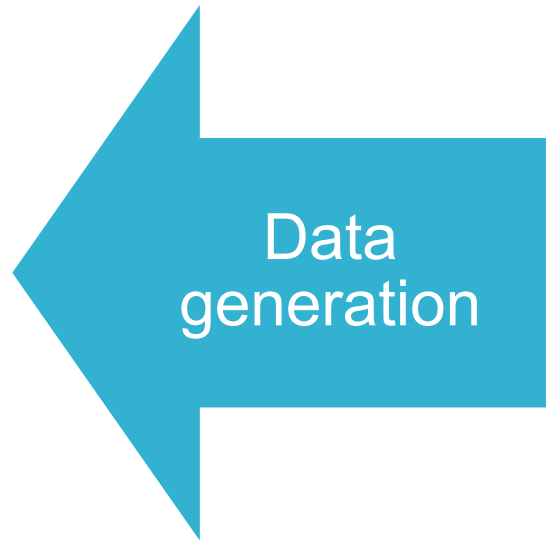
# Concerns With Regulatory Process

---

- Key concerns
  - Rigor vs. pharmaceuticals
  - Impact on patient access
  - Unfamiliarity or inexperience with FDA review designations
  - Ability to account for unique attributes of DTx



# Handling Data Generation & Lifecycle Management



- Responsibility for ownership, security, interoperability
- Patient accessibility and usability
- Patient privacy



- Communication of product updates
- Version control/product discontinuation

# Additional challenges & considerations

- Expertise of the P&T committee & practicing professionals
- Promotion of adoption & equitable access
- Inconsistent inclusion in database and compendium resources
- Economic uncertainties

# Opportunities & Guidance for Stakeholders



# Standardize DTx on 3 Levels

Prescription Status	Product Claim	Levels of Evidence
<ul style="list-style-type: none"><li>• Rx</li><li>• Non-Rx</li></ul>	<ul style="list-style-type: none"><li>• Prevention</li><li>• Treatment</li><li>• Management</li></ul>	<ul style="list-style-type: none"><li>• Sham-controlled</li><li>• Active-comparator</li><li>• RWE pilot</li></ul>



# Follow Guidance for Evidence Development

## Developers

- Demonstrate adequate study design
- Use standards of care comparator, when possible

## Managed Care Decision Makers

- Standardize & make consistent coverage decisions
- Establish expectation for RWE
- Leverage budget impact & cost-effectiveness data

## All

- Utilize Dossier approach
- Exchange information beyond safety & efficacy

# Communicate Product Updates With Intent

When

- Impact to patient care or reimbursement

What

- Effects on safety or efficacy

How

- Develop & utilize re-evaluation standards

# Other Opportunities & Guidance

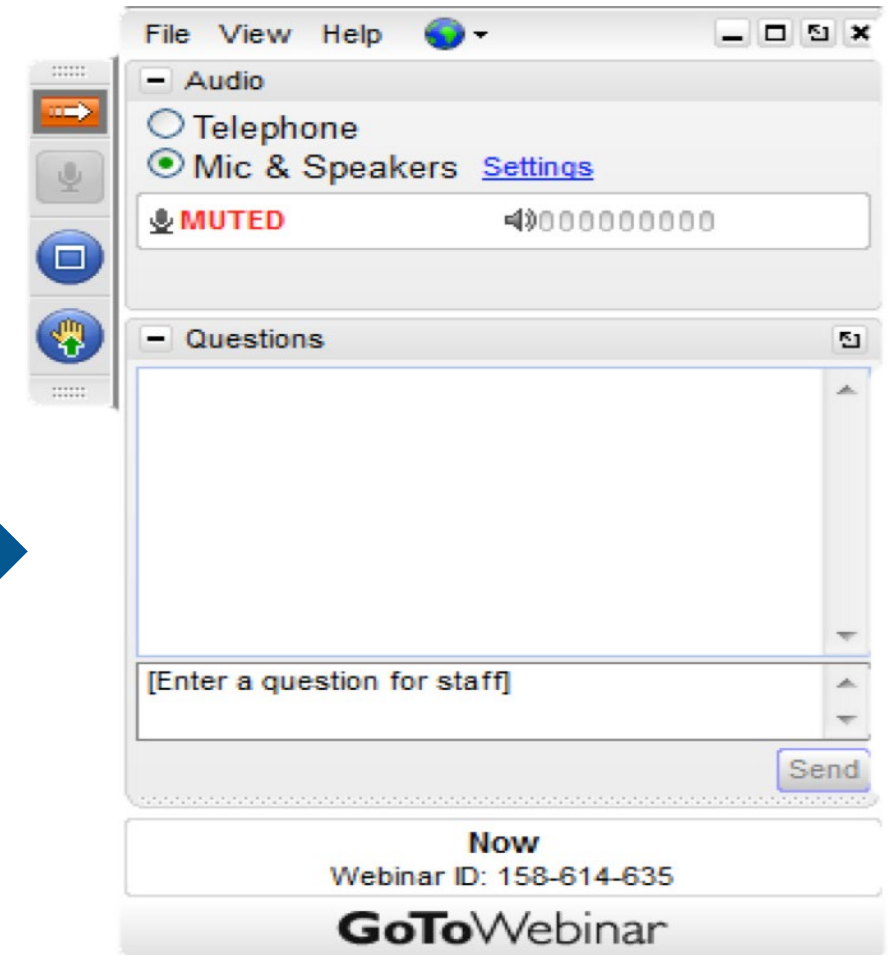
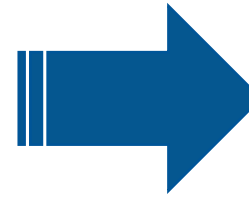
Challenge	Opportunity/Guidance
Expertise of P&T Committee	Incorporate additional expertise
Expertise of practicing professionals	<ul style="list-style-type: none"><li>• Imbed DTx training into curriculum</li><li>• Develop advanced training/CE</li><li>• Publish best practices</li></ul>
Ensuring adoption & equitable access	<ul style="list-style-type: none"><li>• Address provider needs</li><li>• Provide patient education</li><li>• Improve digital health literacy</li></ul>
Inclusion in database/compendia	Encourage inclusion

# What's Next?



# Key forum takeaways

- Standardize definitions and categories
- Emphasize role of regulatory approval
- Establish evidence framework and requirements
- Consider unique DTx product aspects
- Enhance awareness and education of DTx




# Next Steps



Early September 2021


Q2 2022



**PARTNERSHIP FORUM**  
No. 2 ⇨ 2021

**Post Forum Survey**

AUG. 31–SEPT. 1, 2021 | VIRTUAL




**PARTNERSHIP FORUM**  
No. 1 ⇨ 2021

**EXECUTIVE SUMMARY**

**Racial Health Disparities: A Closer Look at Benefit Design**

As disparities due to race, ethnicity, and socioeconomic factors persist in health care, the COVID-19 pandemic brought these disparities to the forefront. In an effort to identify potential structural issues within the current formulary and benefit design processes that can lead to racial health disparities or inequities—and propose viable solutions to reduce these disparities, AMCP convened a virtual multidisciplinary stakeholder forum March 23–24, 2021. The forum included more than 40 experts representing payers, pharmacy benefit managers, integrated delivery systems, health economists and analysts, patient advocates, academicians, biopharmaceutical manufacturers, and other key stakeholders from the managed care setting.

Several principles emerged from the forum discussion as key in efforts to mitigate racial health disparities:

- **Acknowledge that structural racism exists** and impacts the provision of health care, including the formulary development and benefit design processes.
- **Integrate proactive strategies to improve equity**, beginning with education and training throughout health care organizations.
- **View patients holistically** and understand the compounding effect of social determinants of health.

*continued on next page*

**WATCH FOR FOLLOW-UP**

The Partnership Forum is just the beginning of AMCP's efforts around racial health disparities and the role of managed care pharmacy. Our next steps will be to:

- **Publish a proceedings document** on all findings and recommendations from the Partnership Forum in an upcoming issue of AMCP's *Journal of Managed Care + Specialty Pharmacy (JMCP)* and disseminate it widely to decision makers around the country.
- **Host a forthcoming webinar** to report these findings and recommendations.
- **Refocus AMCP's strategic plan** to identify the role that managed care pharmacy can play in recognizing and reducing racial health disparities.
- **Provide educational opportunities** around racial health disparities and examples to prevent them from occurring.
- **AMCP will review and update current policies** to reflect the need for changes in the practice of managed care pharmacy and public policy to address racial health disparities.

**CONTACT INFO**  
675 N Washington Street | Suite 220  
Alexandria, VA 22314  
703 684 2600 | [www.amcp.org](http://www.amcp.org) | [@amcporg](https://twitter.com/amcporg)  
AMCP | Academy of Managed Care Pharmacy

December 2021  
Volume 24 Number 12

**JMCP**  
JOURNAL OF  
Managed Care +  
Specialty Pharmacy

**IN THIS ISSUE**

**Population-based utilization and costs associated with routine breast ultrasound for breast cancer screening in older women with comorbidities**  
J. Lee, J. Gierke, M. W. Lee, et al.

**Adverse health care resource utilization and cost among type 2 diabetes patients with newly diagnosed chronic kidney disease: a retrospective cohort study**  
J. H. Lee, J. H. Lee, J. H. Lee, et al.

**A regional analysis of payer and provider rates on pharmaceutical management (PAM) initiatives as an alternative alignment model**  
J. H. Lee, J. H. Lee, J. H. Lee, et al.

**Assessing the association between medication adherence, as defined on quality measures, and disease state control: health care utilization, and costs in a retrospective database analysis of Medicare supplemental beneficiaries using insulin medications**  
J. H. Lee, J. H. Lee, J. H. Lee, et al.

**Incidence and prevalence of systemic sclerosis and systemic sclerosis with interstitial lung disease in the United States**  
J. H. Lee, J. H. Lee, J. H. Lee, et al.

**Utilization and outcomes in the United States: a systematic review of JCR reports to evaluate trends, identify factors associated with noncompliance, and understand implications**  
J. H. Lee, J. H. Lee, J. H. Lee, et al.

**Pharmacist-provided care in statewide pharmacy organizations: findings from the Michigan Pharmacist Transforming Care and Quality Collaborative**  
J. H. Lee, J. H. Lee, J. H. Lee, et al.

**Incremental clinical and economic impact of noninvasive positive ventilation: cost and effect in a budget impact analysis**  
J. H. Lee, J. H. Lee, J. H. Lee, et al.

**Cost of apixone-related health care encounters in the United States**  
J. H. Lee, J. H. Lee, J. H. Lee, et al.

**Prescribing rates and characteristics of new users of lamotrigine-containing regimens before and after the first entry of lamotrigine monotherapy**  
J. H. Lee, J. H. Lee, J. H. Lee, et al.

**The use of real-world evidence in JCR's ongoing projects and clinical research environments**  
J. H. Lee, J. H. Lee, J. H. Lee, et al.

**Barriers, solutions, and effect of using pharmacogenetics data to support opioid prescribing**  
J. H. Lee, J. H. Lee, J. H. Lee, et al.

**JMCP 25th ANNIVERSARY**  
Is real-world evidence used in PAM? Insights and perspectives from the field  
J. H. Lee, J. H. Lee, J. H. Lee, et al.

**Real-world evidence enhances decision-making**  
J. H. Lee, J. H. Lee, J. H. Lee, et al.

JMCP's mission is to advance science, expertise, and evidence-based decision-making to improve patient health through access to high-quality, cost-effective medications and other therapies.



# Thank You to Our Sponsors

---

HOSTED BY AMCP IN PARTNERSHIP WITH

---

**AKILI**

 **PEAR**  
THERAPEUTICS

 **Pfizer**

**PhARMA**  
RESEARCH • PROGRESS • HOPE

**SIMON ♦ KUCHER & PARTNERS**  
Strategy & Marketing Consultants

 **Takeda**

**theranica**

 **Woebot**<sup>®</sup>  
Health





## Mission

To improve patient health by ensuring access to high-quality, cost-effective medications and other therapies.