AMCP

PARTNERSHIP FORUM

No. 2 — 2021

Digital Therapeutics:
The Evolving Role of Digital Therapeutics

AUG. 31–SEP. 1, 2021

Moderator Welcome

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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

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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

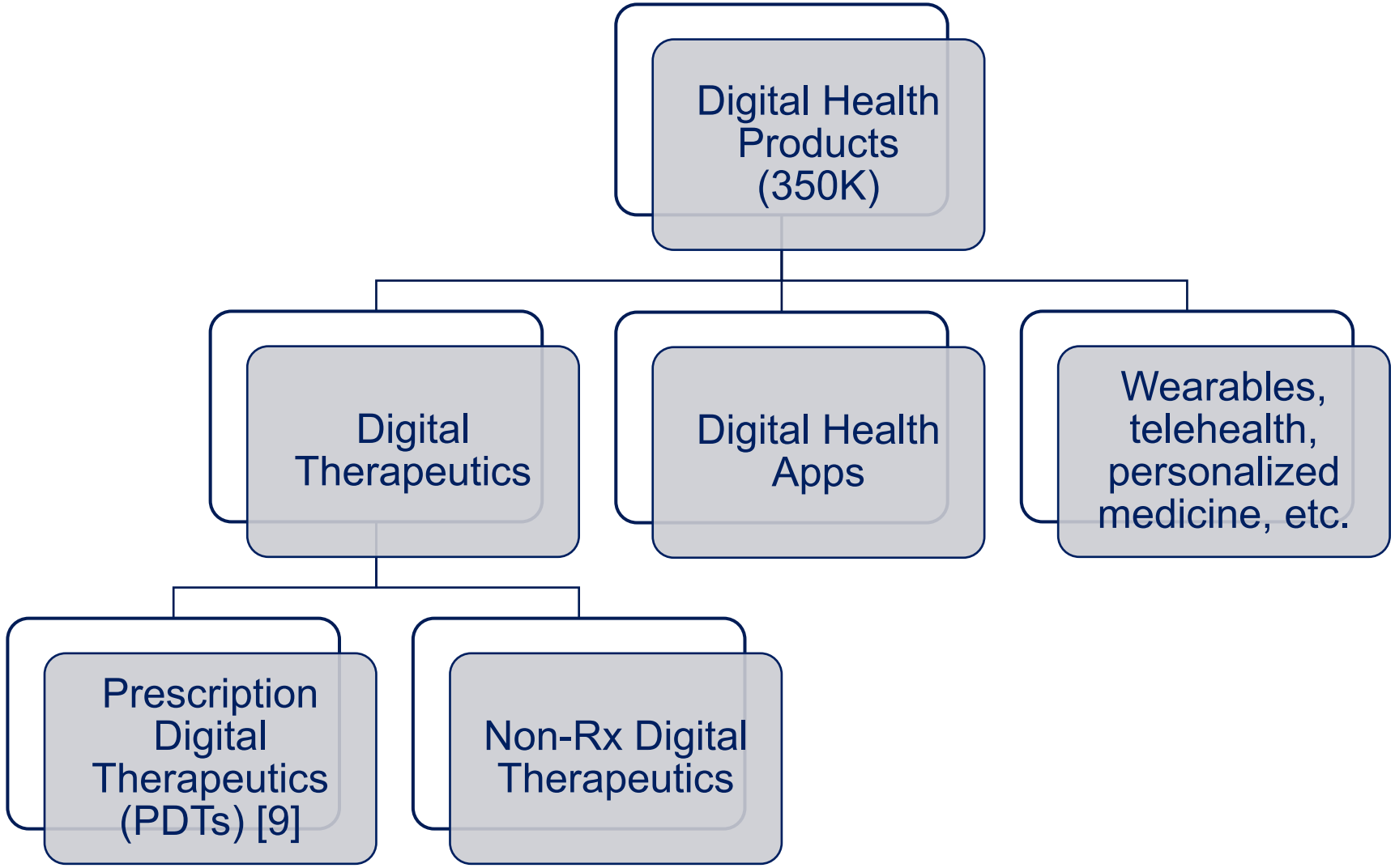
What are DTx?

- *"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

J Manag Care Spec Pharm. 2020;26(5):674-81. doi: 10.18553/ jmcp.2020.19418; https://dtxalliance.org/wp-content/uploads/2021/01/DTA_FS_DTx-Product-Categories_010521.pdf

DTx ≠ Digital Health

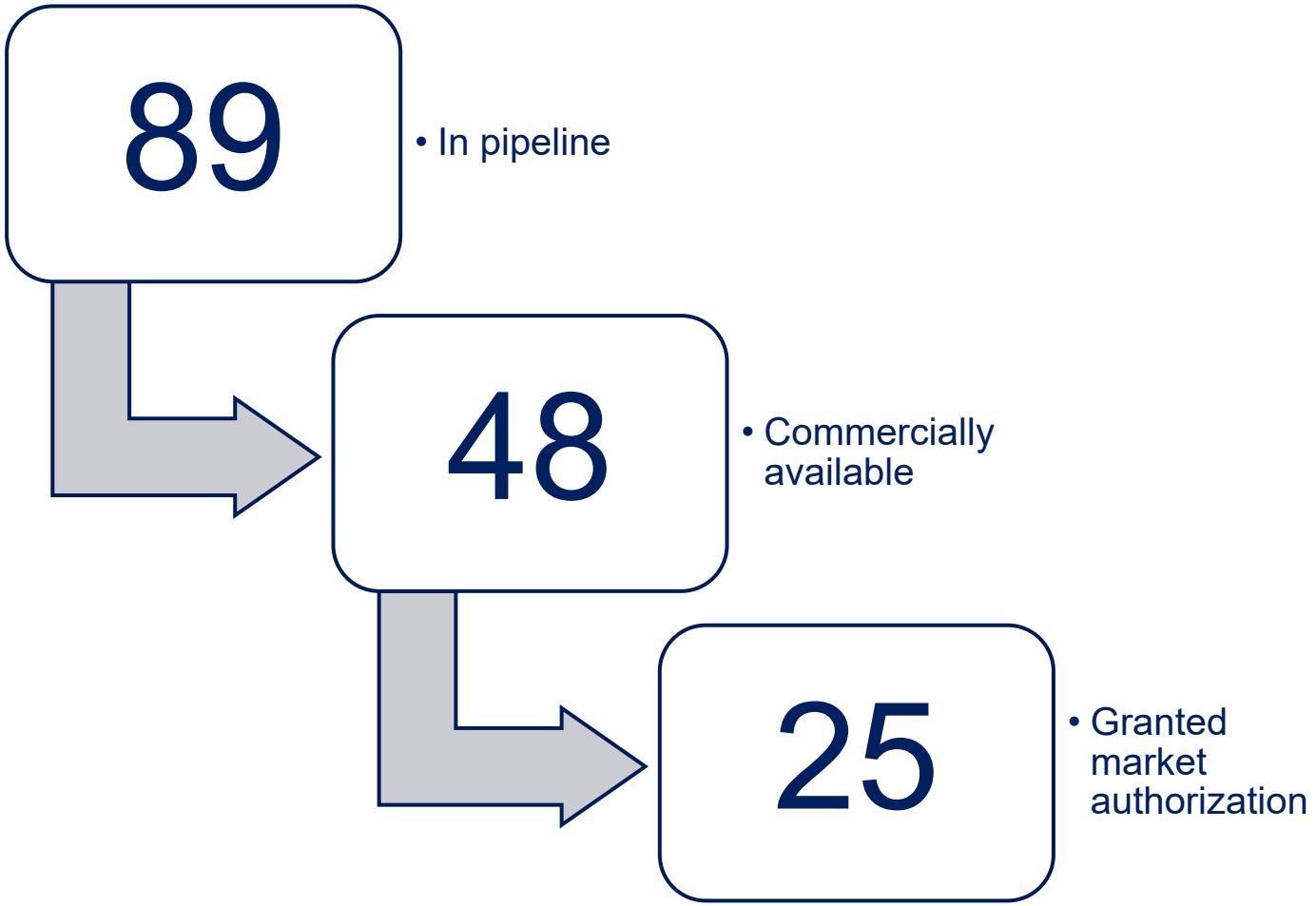


Key Differences Between DTx & Digital Health Apps

Digital Therapeutics	Digital Health Apps
Regulated	Unregulated
May make efficacy claim	No efficacy claim
*Three pathways for market authorization: • 510(k) • De Novo Classification • Precertification (Pre-Cert)	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

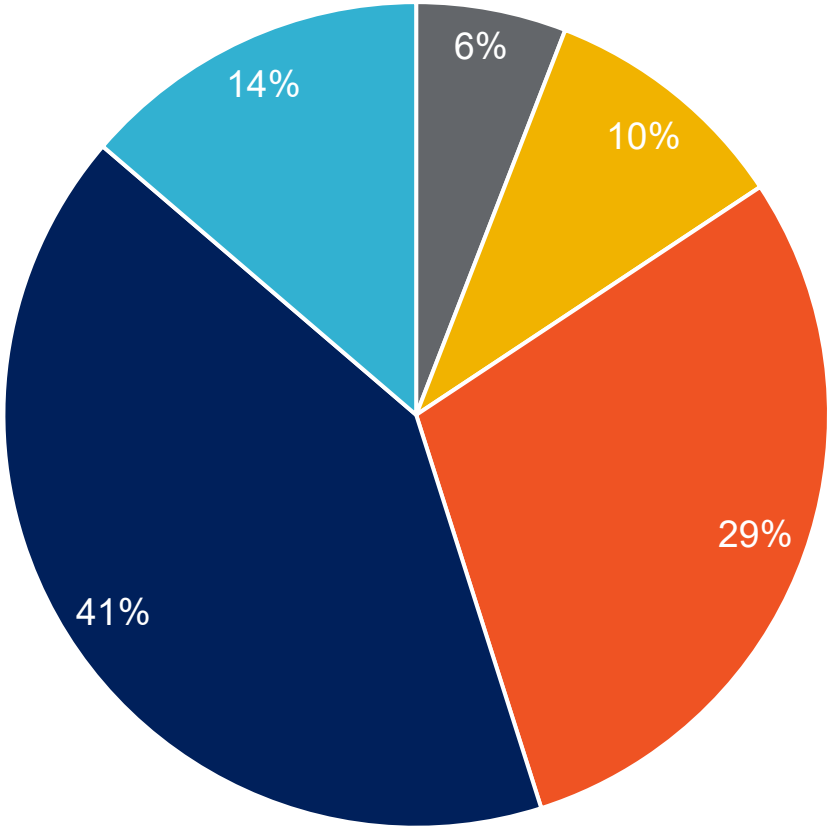
Understanding Stakeholder Perspectives on Digital Therapeutics

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)

1 Not at all
2 Slightly
3 Mildly
4 Moderately
5 Rapidly

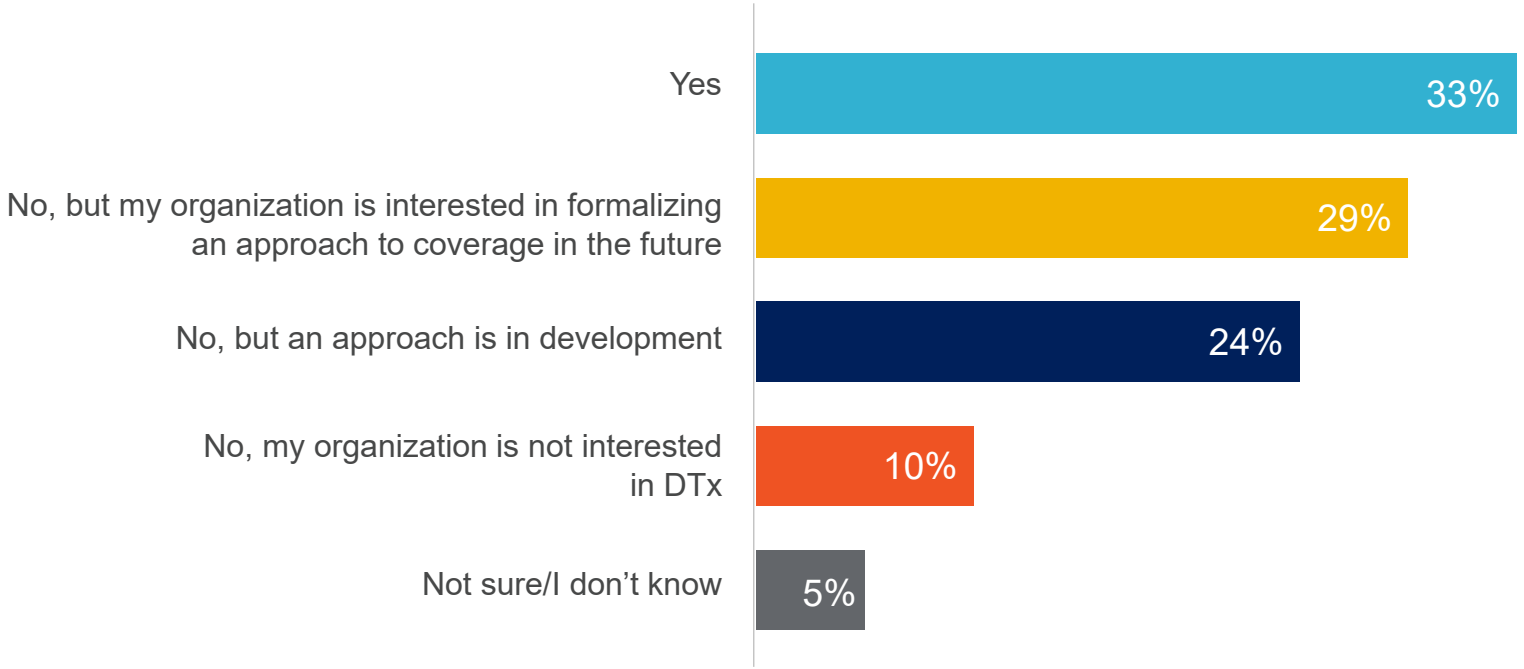


N=51 Respondents

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

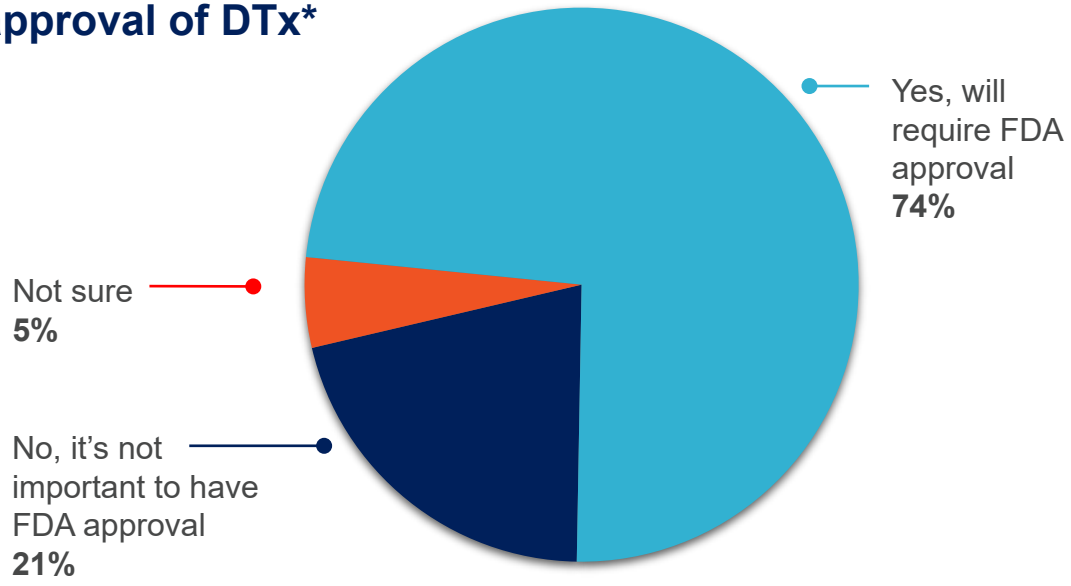
85% of payer respondents either had a defined approach for covering DTx, or were planning to implement one

N=21 Payer Respondents
DTx = digital therapeutics.

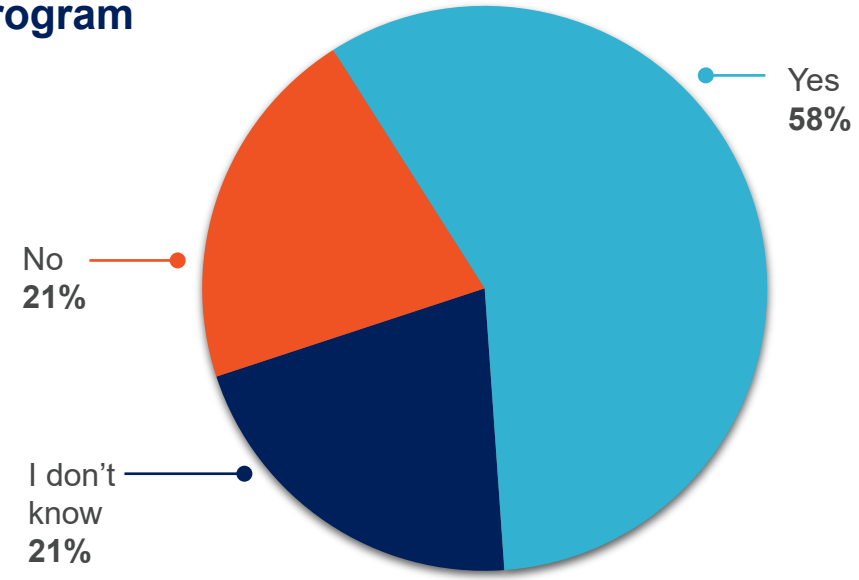
Most payer respondents indicated a desire for meaningful evidence

PAYER RESPONDENTS

Requirement for FDA approval of DTx*



Requirement for pilot program



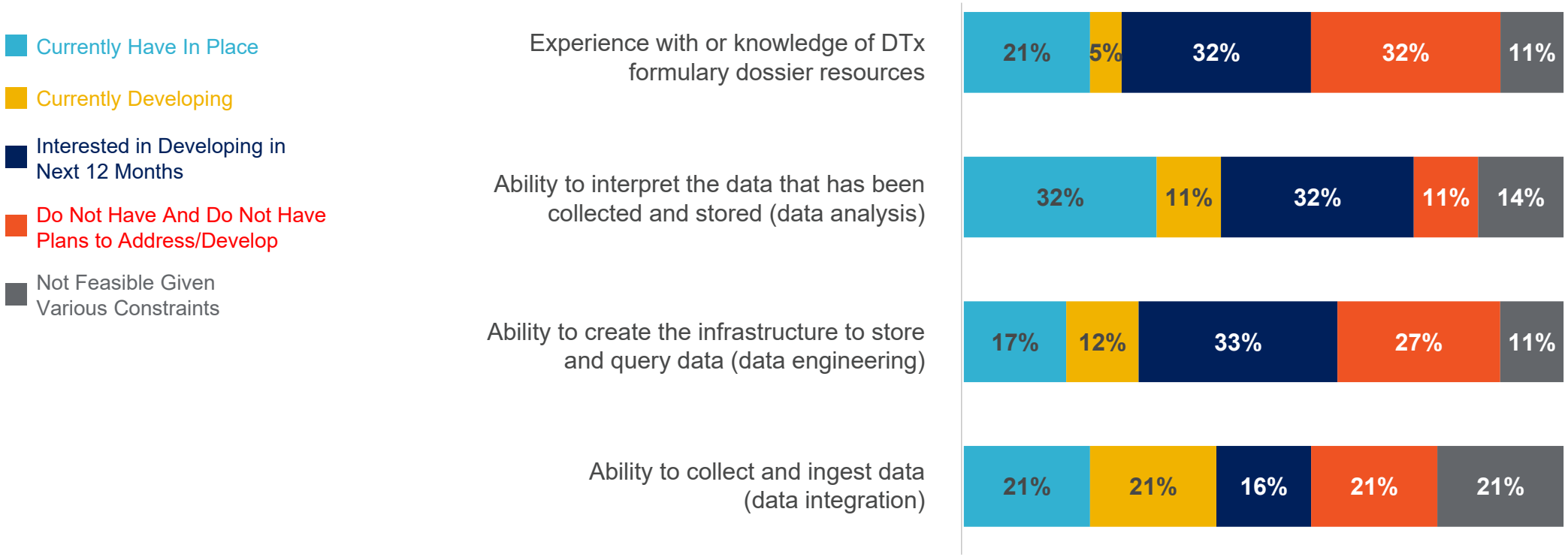
N=19 Payer Respondents
FDA = U.S. Food and Drug Administration.

POINT OF INTEREST

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

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

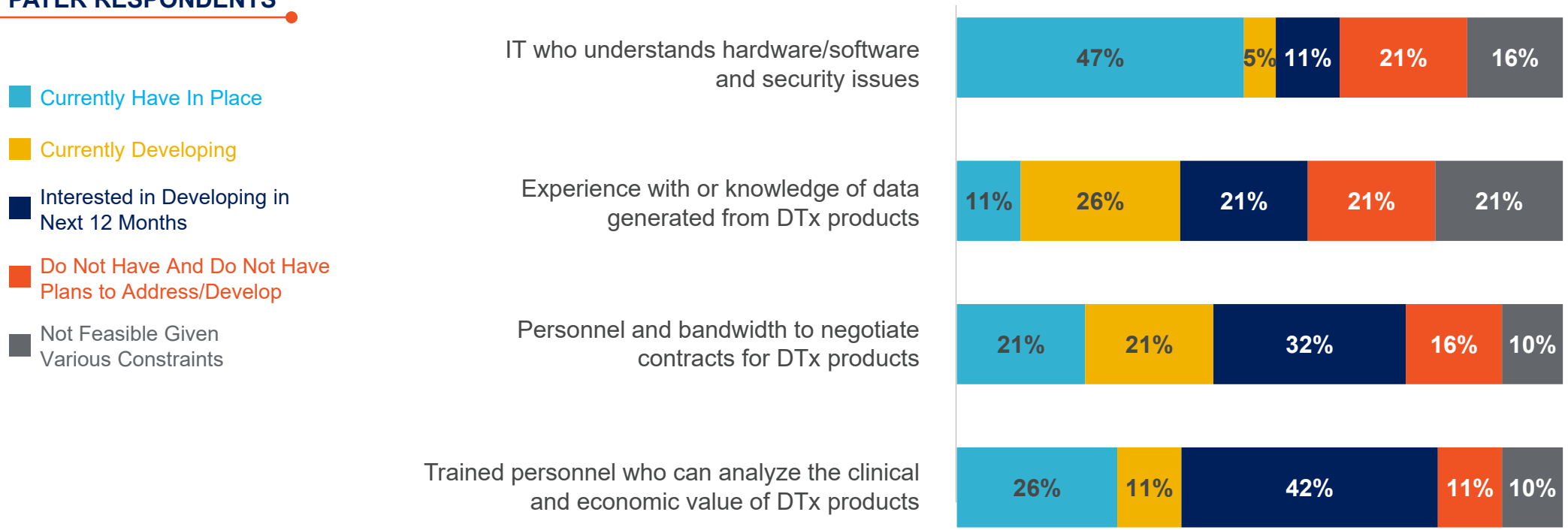
PAYER RESPONDENTS



N=21 Payer Respondents

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

PAYER RESPONDENTS



N=21 Payer Respondents

POINT OF INTEREST

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

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.

22

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
• Rx • Non-Rx	• Prevention • Treatment • Management	• Sham-controlled • Active-comparator • RWE pilot

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

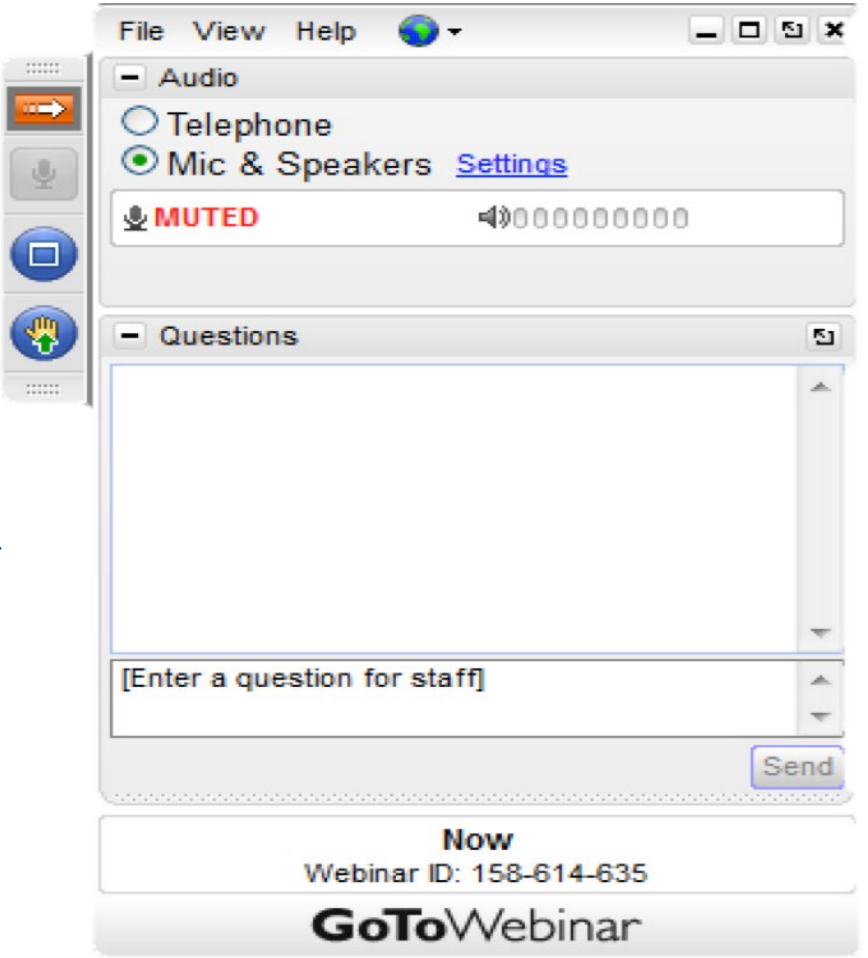
Other Opportunities & Guidance

Challenge	Opportunity/Guidance
Expertise of P&T Committee	Incorporate additional expertise
Expertise of practicing professionals	• Imbed DTx training into curriculum • Develop advanced training/CE • Publish best practices
Ensuring adoption & equitable access	• Address provider needs • Provide patient education • Improve digital health literacy
Inclusion in database/compendia	Encourage inclusion

What's Next?

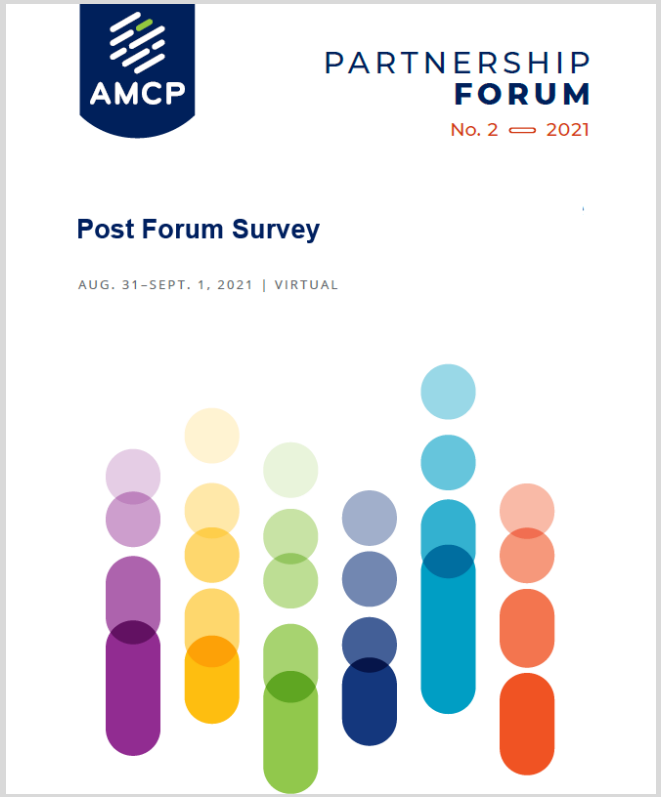
Key forum takeaways

- 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



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