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# Paying for Digital Therapeutics: What Evidence is Needed

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# Moderator and Speakers



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MBA**

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Enterprise Strategy  
Director  
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Senior Manager,  
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**Zachary A Zalewski,  
Mchem, MBA**

CEO  
Digital Medicine  
Society (DiMe)

# Poll Question

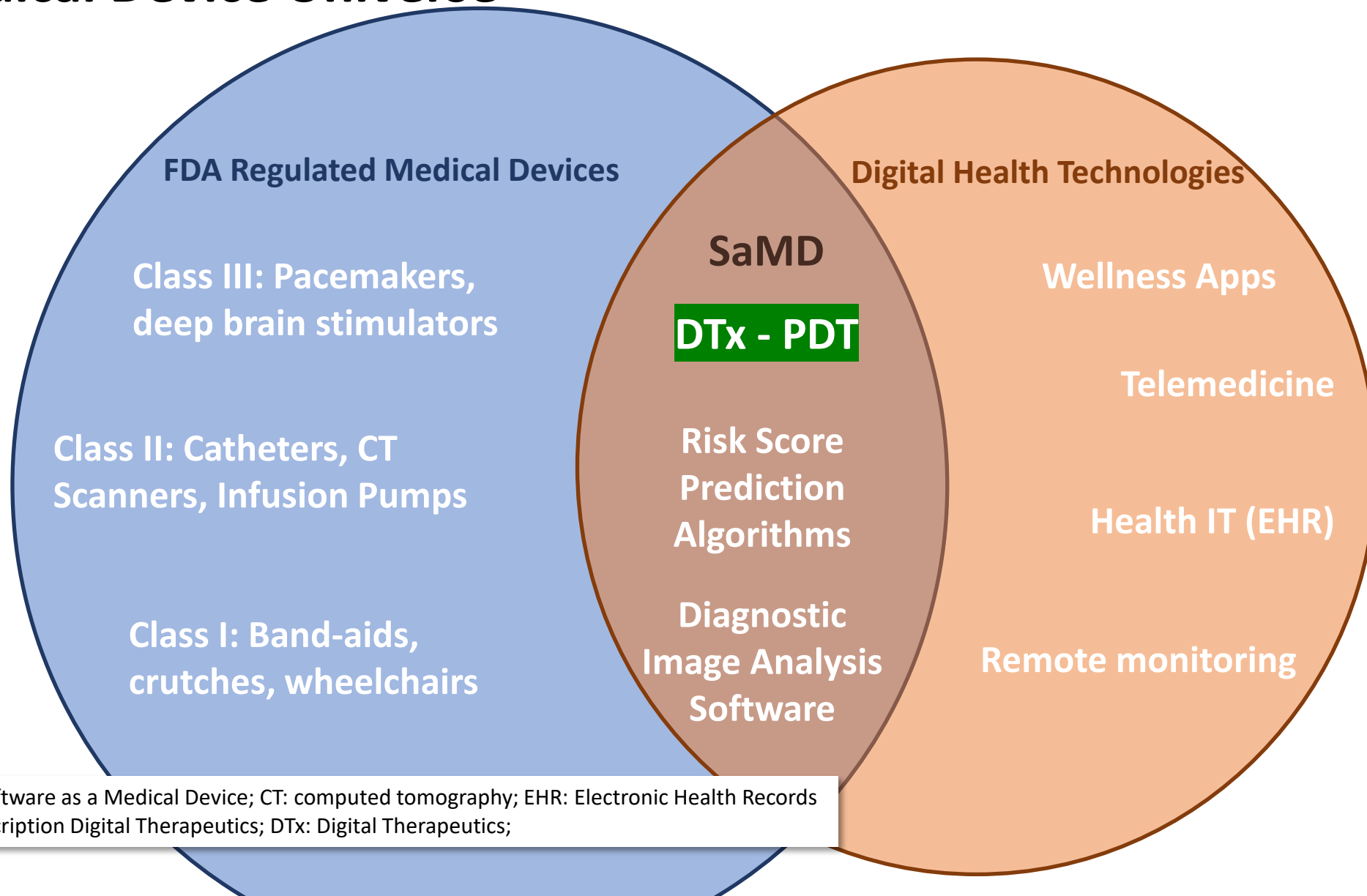
- What word(s) come to mind when you think of DTx?



**Zachary A Zalewski, PhD, JD**

Enterprise Strategy Director  
US Pharmacopeia

# DTx Contemplates a Large (and Growing!) and Overlapping Medical Device Universe



SaMD: Software as a Medical Device; CT: computed tomography; EHR: Electronic Health Records  
PDT: Prescription Digital Therapeutics; DTx: Digital Therapeutics;

# Medical Devices are Subject to FDA Regulation, Which Includes Evidentiary Requirements

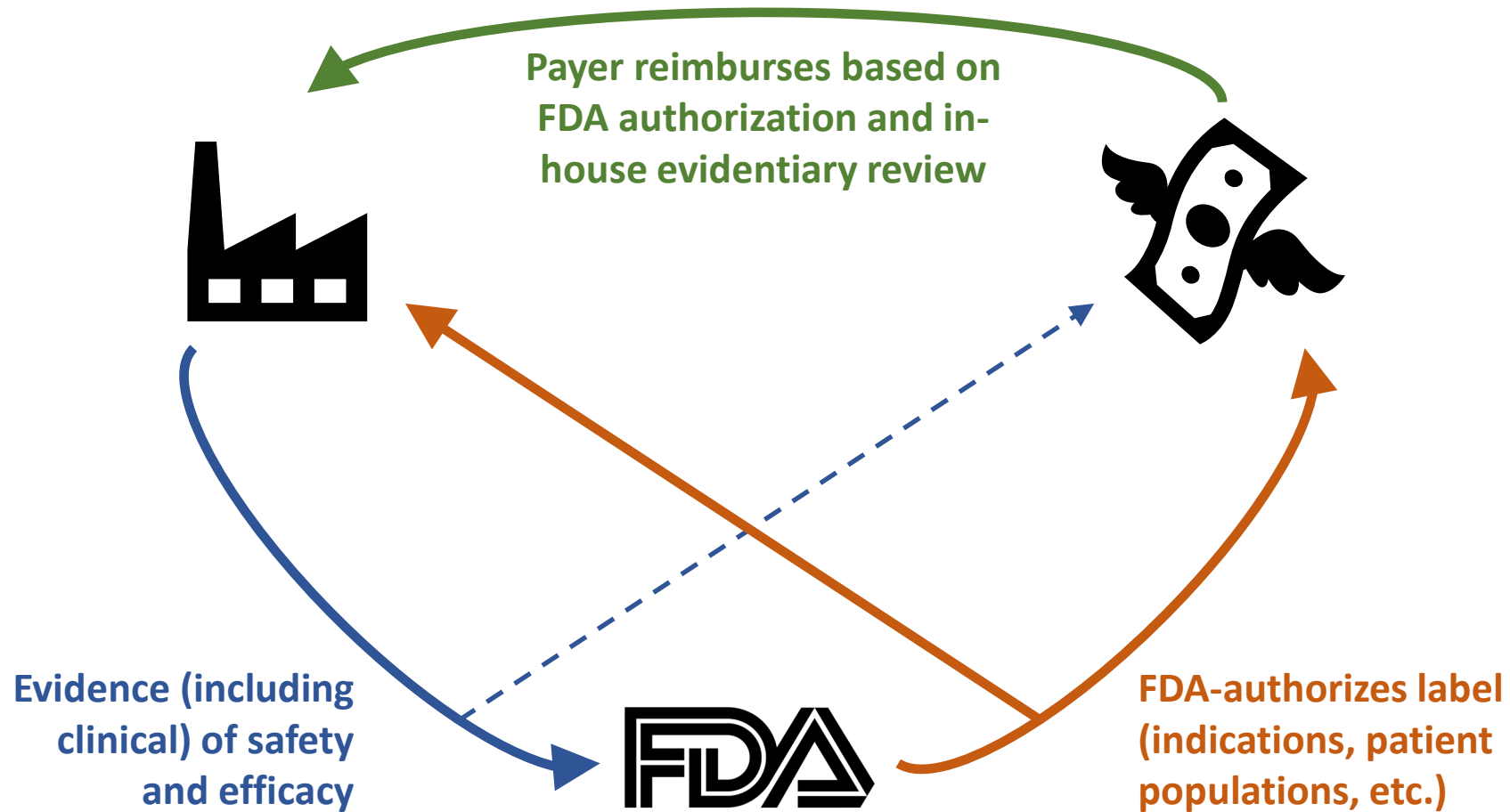
- “intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or... intended to affect the structure or any function of the body of man or other animals”\*
- “the effectiveness of a device is... determined... on the basis of well-controlled investigations, including 1 or more clinical investigations where appropriate...”\*\*

\*\*Federal Food, Drug & Cosmetic Act Section 513(a)(3)(A)

\*Federal Food, Drug & Cosmetic Act Section 201(h)(1)(b), (c)



# Sponsors Provide FDA with Safety & Efficacy Evidence; FDA Authorization Gives Payers Certainty





## **Vyishali Dharbhamalla, PharmD**

Senior Manager, Professional Affairs  
Academy of Managed Care Pharmacy

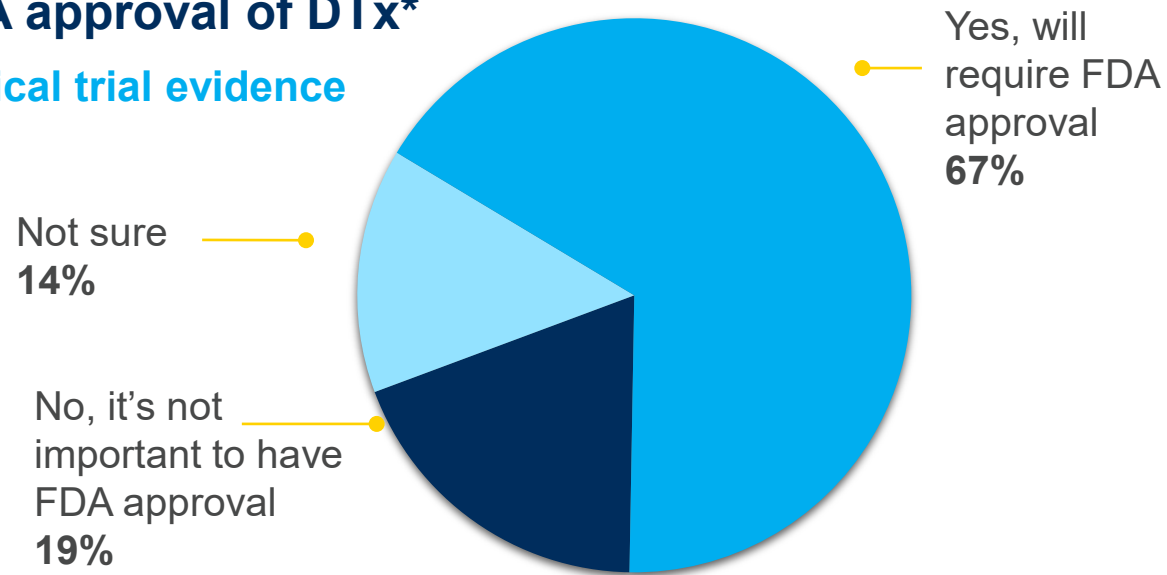
# 67% of payers require FDA approval



## PAYER RESPONDENTS

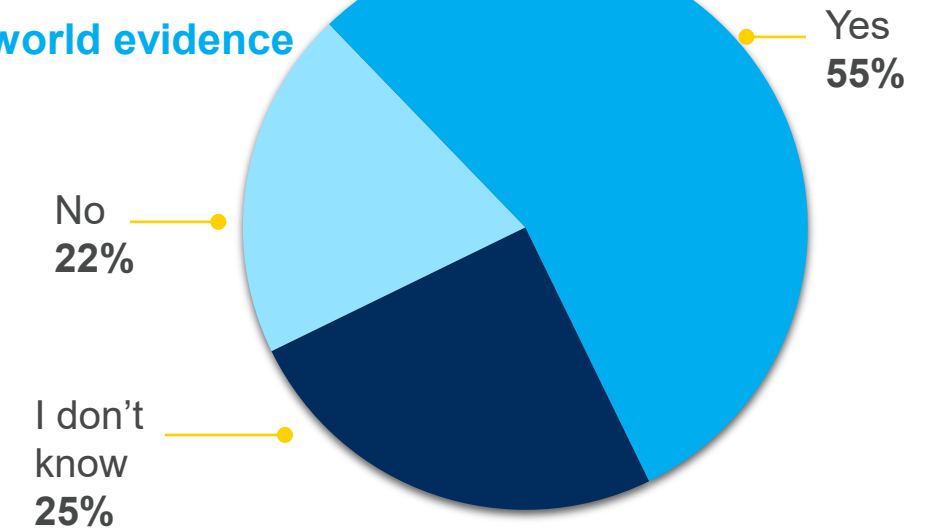
### Requirement for FDA approval of DTx\*

#### Clinical trial evidence



### Requirement for pilot program†

#### Real-world evidence



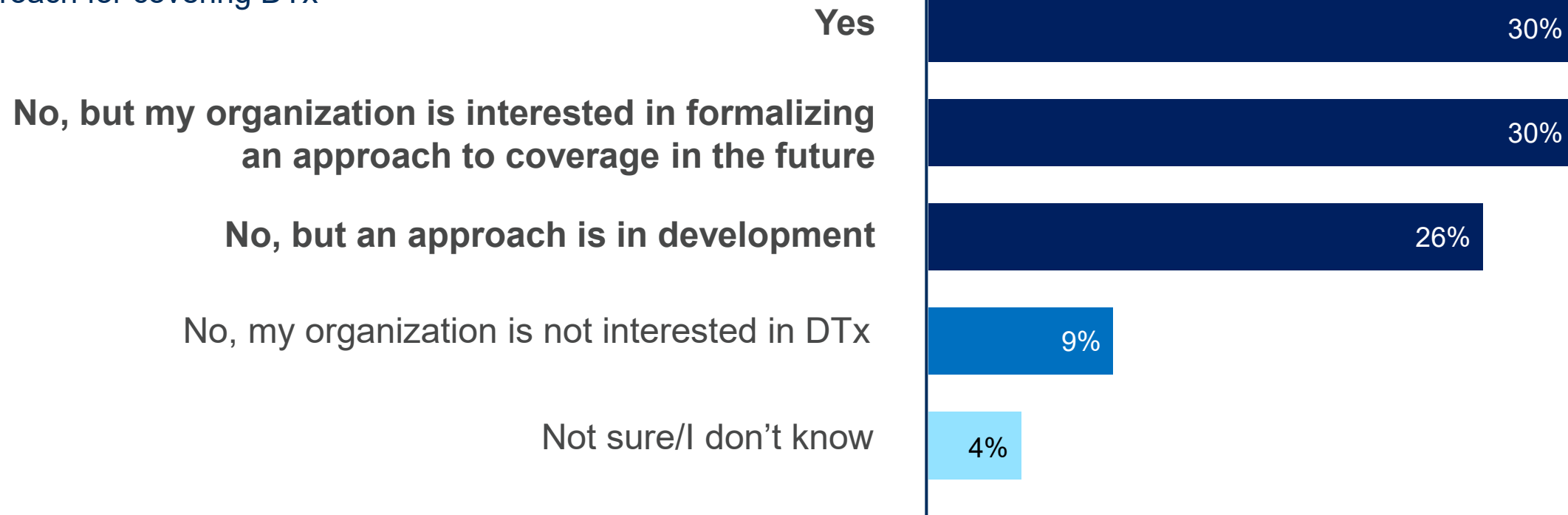
AMCP/Cyan Health Survey: August 2021  
\*N=21 Payer Respondents  
†N=20 Payer Respondents  
FDA = U.S. Food and Drug Administration.

# 86% of payers have (or plan to have) a defined approach for covering DTx



## PAYER RESPONDENTS

% of payers with a defined approach for covering DTx

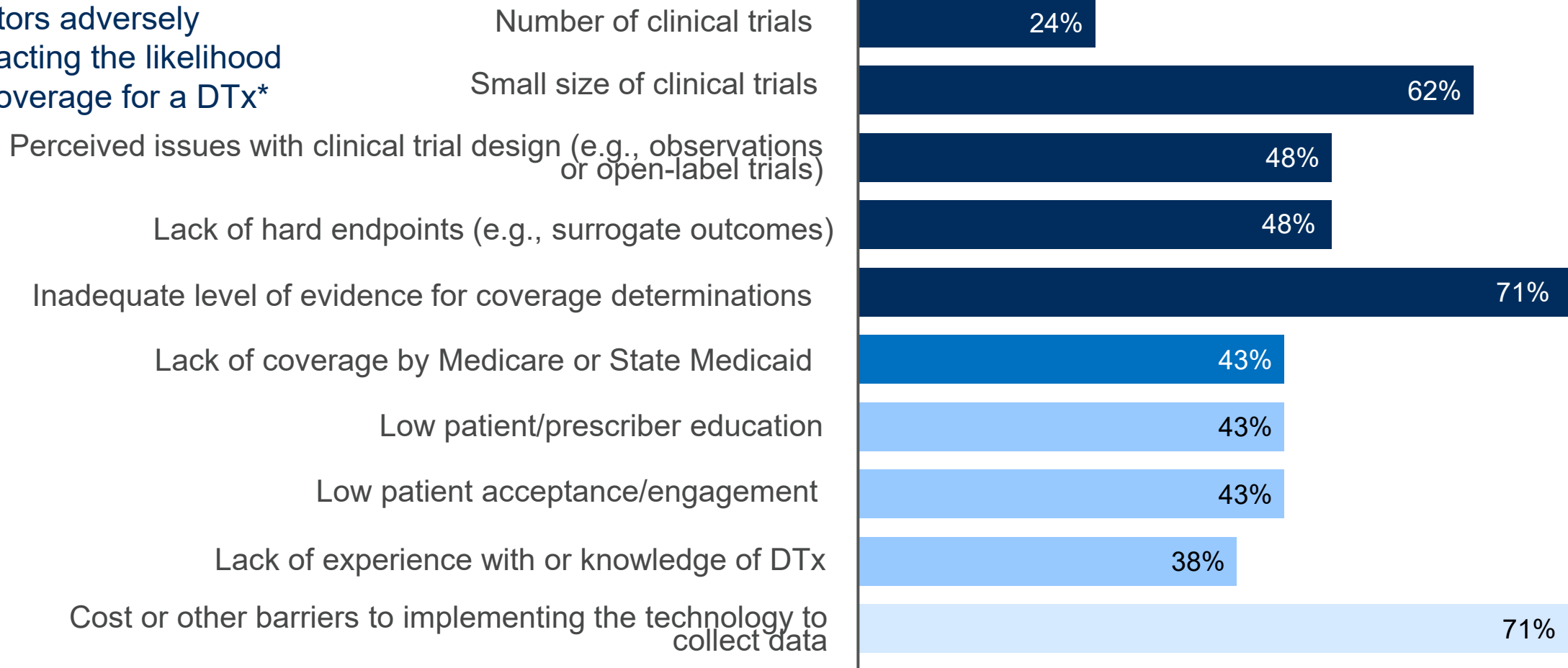


# Evidentiary, benefit inclusion, education, and IT infrastructure challenges exist



## PAYER RESPONDENTS

Factors adversely impacting the likelihood of coverage for a DTx\*



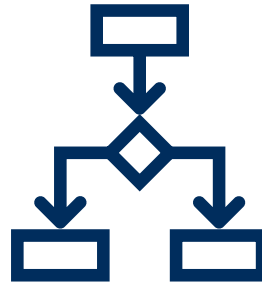
AMCP/Cyan Health Survey: August 2021 N=21 Payer Respondents

\*This was a "select all that apply" question.

# What we need:



More and better evidence



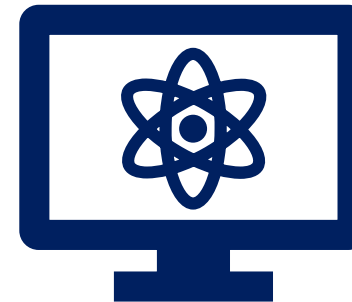
Evidence Framework



P&T Committee Supplementation



Education



IT Integration

Payers are moving towards coverage of prescription DTx, but need clinically meaningful evidence, benefit inclusion, education, and IT infrastructure changes.



Jennifer Goldsack

CEO  
Digital Medicine Society (DiMe)

# Advancing digital health applications



# Advancing digital health applications

## Global priorities for innovation in real-world evidence (RWE) generation

Topic areas where precompetitive collaboration, research, and the development of best practices will speed broad acceptance of high-quality evidence to support digital health applications

- Missing data
- Study endpoints
- Comparator group
- Multimodal interventions
- Study question
- Equity
- Generalizability
- Confounders
- Fit-for-purpose






# European digital health regulatory landscape is soaring

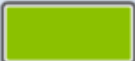
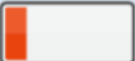
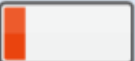
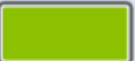
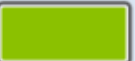
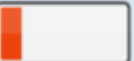

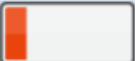
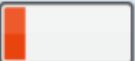
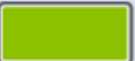
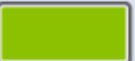
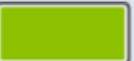

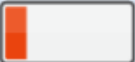
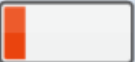



- In Oct'21, **France's** President announced plans to replicate the DiGA reimbursement scheme
- In Nov'21, **European Council** agreed on a new, harmonised regulation on health technology assessments across EU
- In partnership between ORCHA and 7 ICS, now 5.6 million people in England will have access to digital health libraries.
- Belgium, Denmark, Finland, Scotland, Ireland, Luxemburg, Spain and Sweden are discussing market access for reimbursable medical apps



# So is Asia-pacific region making strides...

- In Mar'20 **Australia's** TGA released a comprehensive overview of software products qualifications and selection requirements. In Feb'21, they also released their SaMD classification.
- **Japan's** MHLW and PMDA launched a process called "SAKIGAKE", which allows for accelerated regulatory pathways for products designated as breakthrough devices addressing high, unmet medical needs
- **Singapore's** Health Sciences Authority (HSA) has published guidelines on software medical devices with intentions to

-  current regulatory framework encompasses the recommended best practices.
-  some guideline is currently available, however, further improvements are recommended.
-  the best practices are not currently adopted.

	Qualification	Risk Classification	Software with Multiple Functions	Alternative Pathways for DH	Pre-submission Consultation	Framework for AI/ML
<b>Best Practices</b>	Software must have an intended purpose that fulfils the definition of a medical device in order to qualify as a medical device.	IMDRF's N12 guidance describes that the two key factors that should be taken into account when assessing the risk categorization of a SaMD product are:  1. State of the healthcare situation or condition that the SaMD is intended for.  2. The significance of the information that is provided by the SaMD to the healthcare decision.	For software products with multiple functions, regulatory authorities exercise oversight only over those functions with an intended purpose that fulfils the medical device definition.	Approaches to regulatory review that are tailored to the unique needs of DH products.	Opportunity to engage with regulatory authorities prior to premarket submission review.	Guidance and/or framework describing the regulation of AI/ML technologies.
<b>Australia (TGA)</b>						
<b>Japan (PMDA)</b>						
<b>Singapore (HSA)</b>						

Regulatory process aren't the limiting factor for digital innovation. Rather an optimal regulatory strategy is critical part of successful digital product strategy

# Poll Question

- What do you think is the most challenging aspect for DTx uptake?
  - A) Trial data does not exist for DTx
  - B) Lack of RWE for DTx
  - C) Manufacturer ability to articulate value proposition
  - D) Payer readiness to evaluate DTx