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Paying for Digital Therapeutics: What Evidence is Needed

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Moderator and Speakers

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Co-lead Key Project
Digital Health SIG

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Enterprise Strategy Director
US Pharmacopeia

Vyishali Dharbhamalla, PharmD

Senior Manager, Professional Affairs
AMCP

Zachary A Zalewski, Mchem, MBA

CEO
Digital Medicine Society (DiMe)

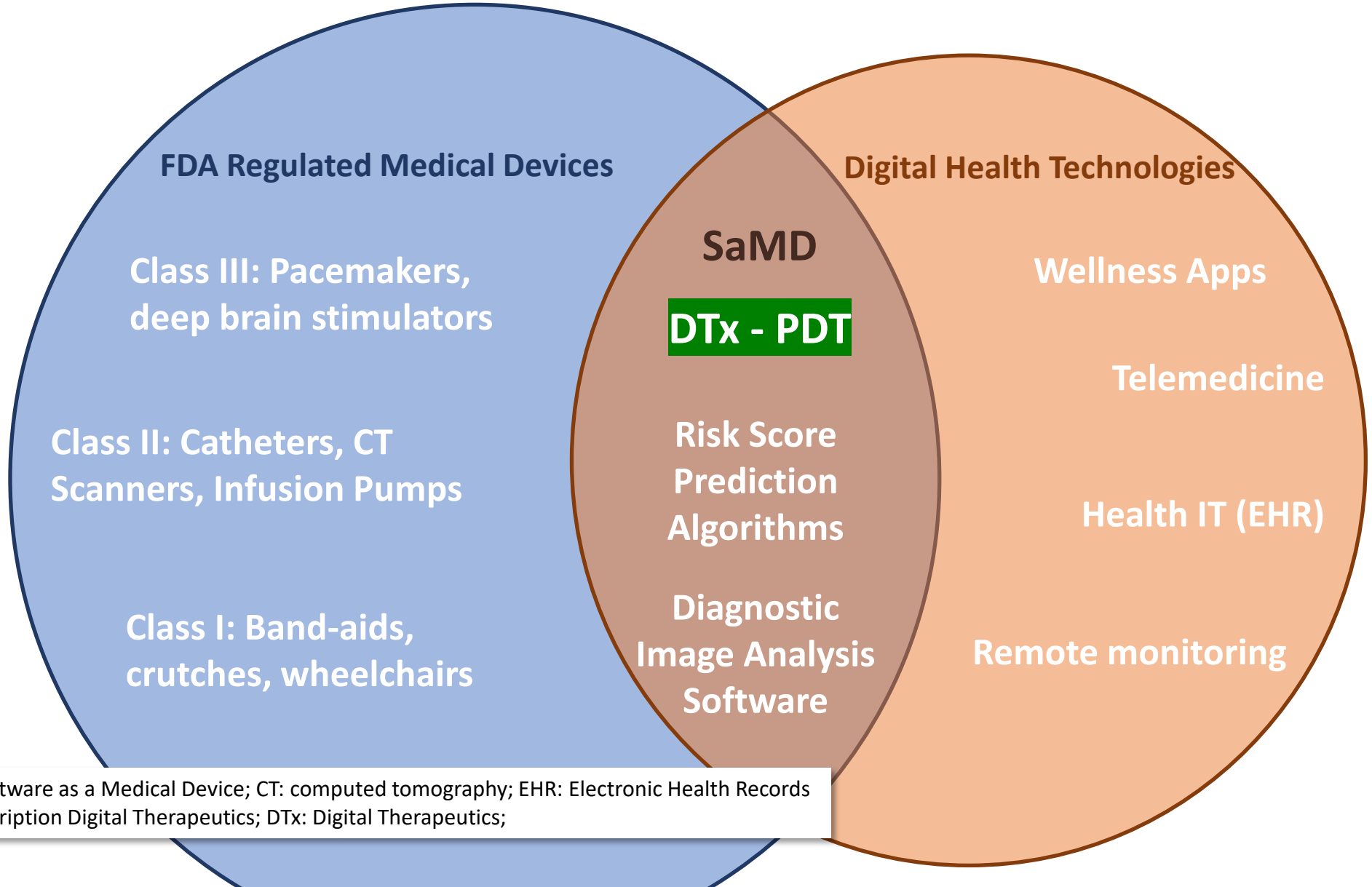
Poll Question

- 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



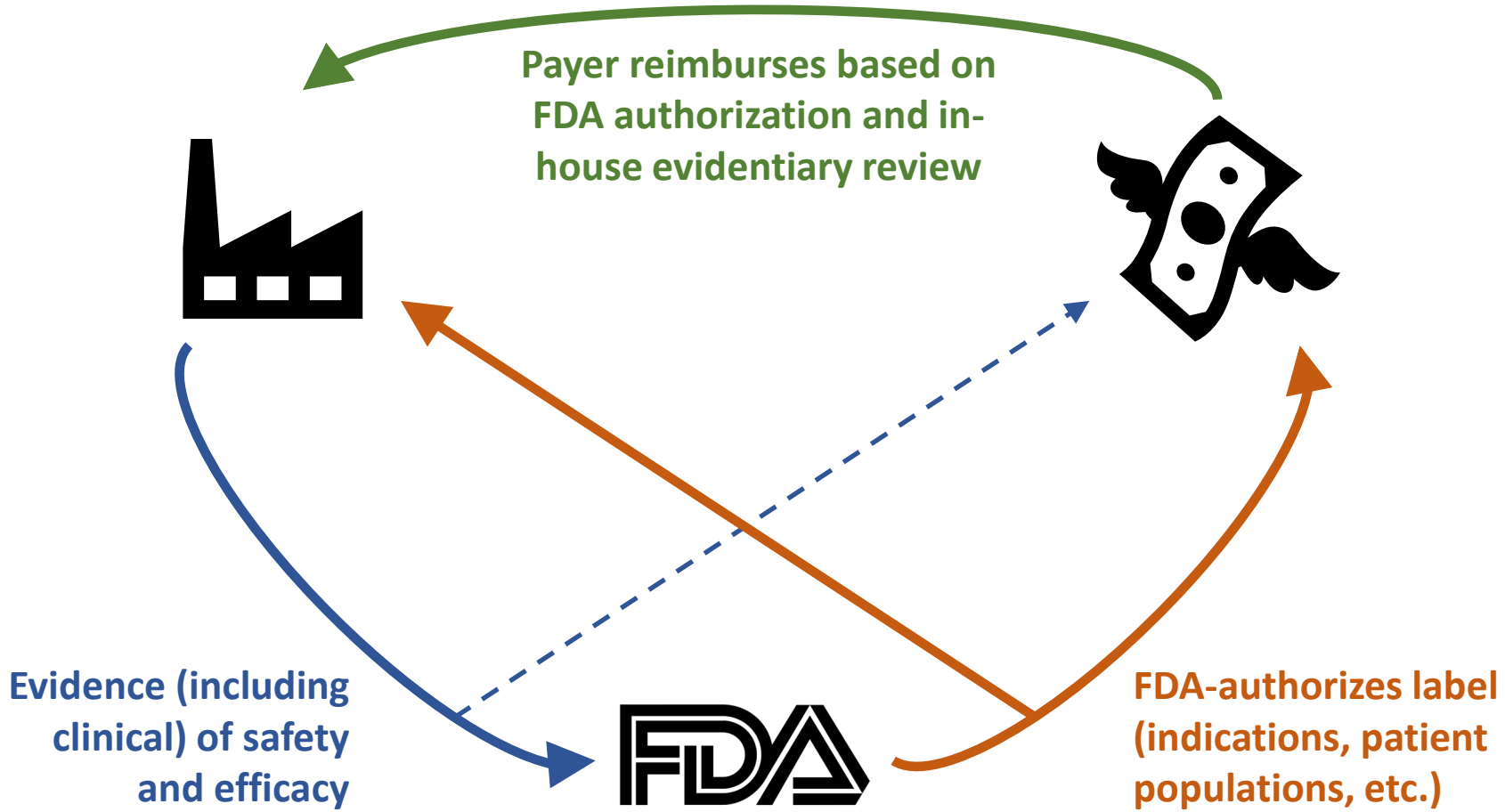
SaMD: Software as a Medical Device; CT: computed tomography; EHR: Electronic Health Records
PDT: Prescription Digital Therapeutics; DTx: Digital Therapeutics;

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

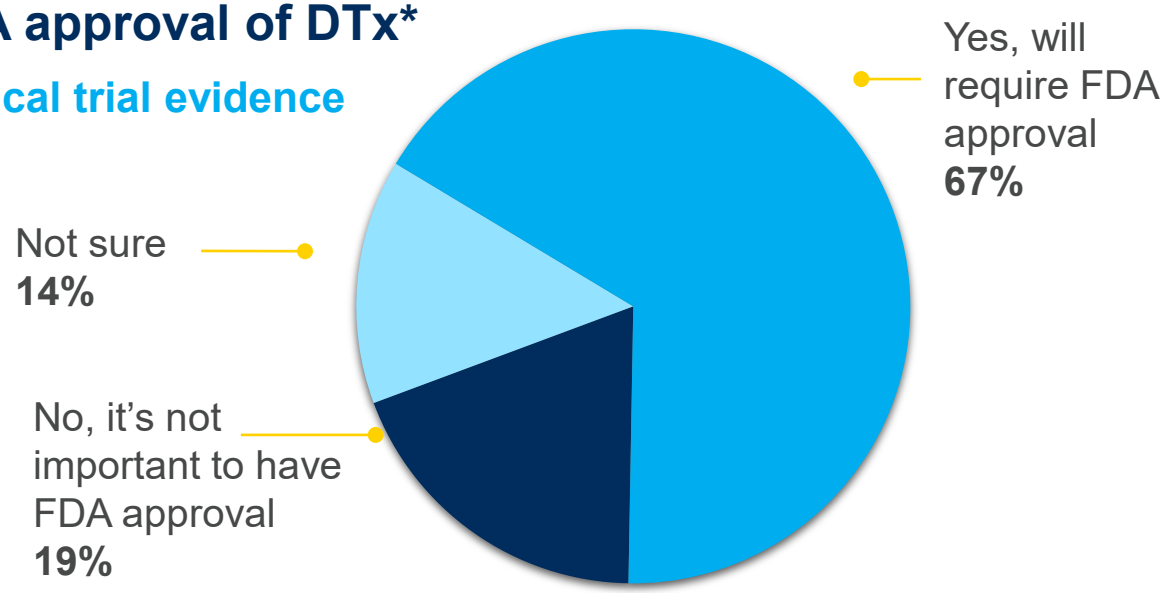
Senior Manager, Professional Affairs
Academy of Managed Care Pharmacy

67% of payers require FDA approval

PAYER RESPONDENTS

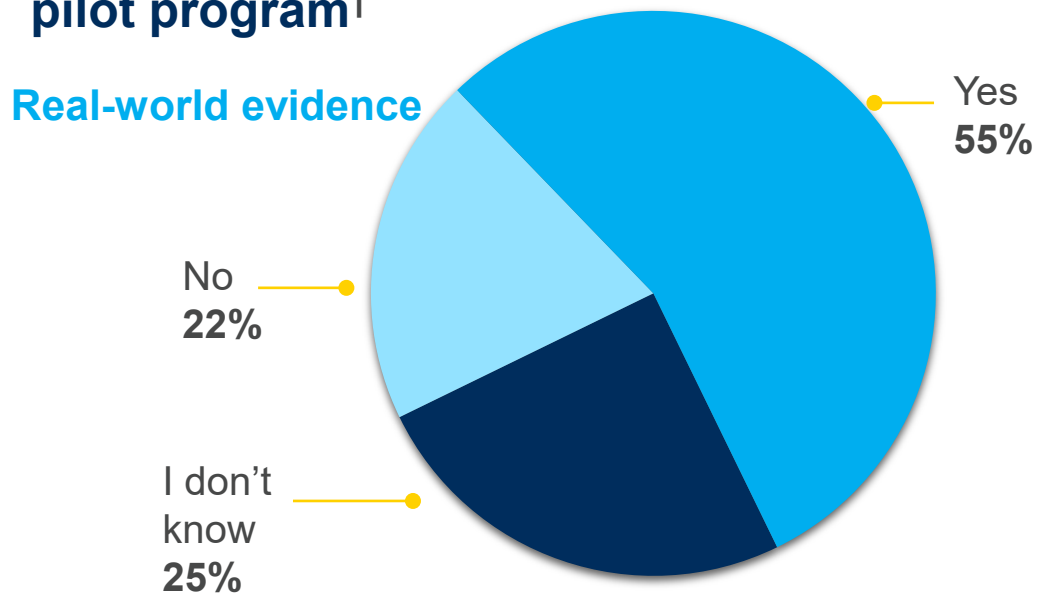
Requirement for FDA approval of DTx*

Clinical trial evidence



Requirement for pilot program†

Real-world evidence

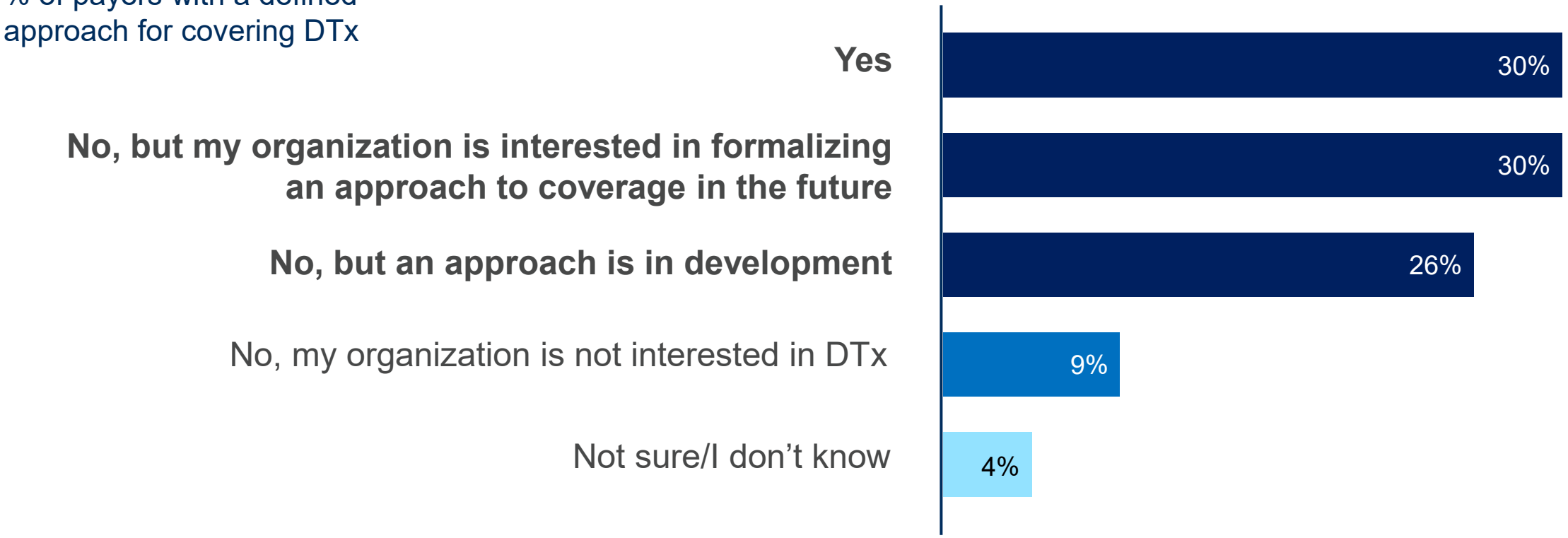


AMCP/Cyan Health Survey: August 2021
*N=21 Payer Respondents
†N=20 Payer Respondents
FDA = U.S. Food and Drug Administration.

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

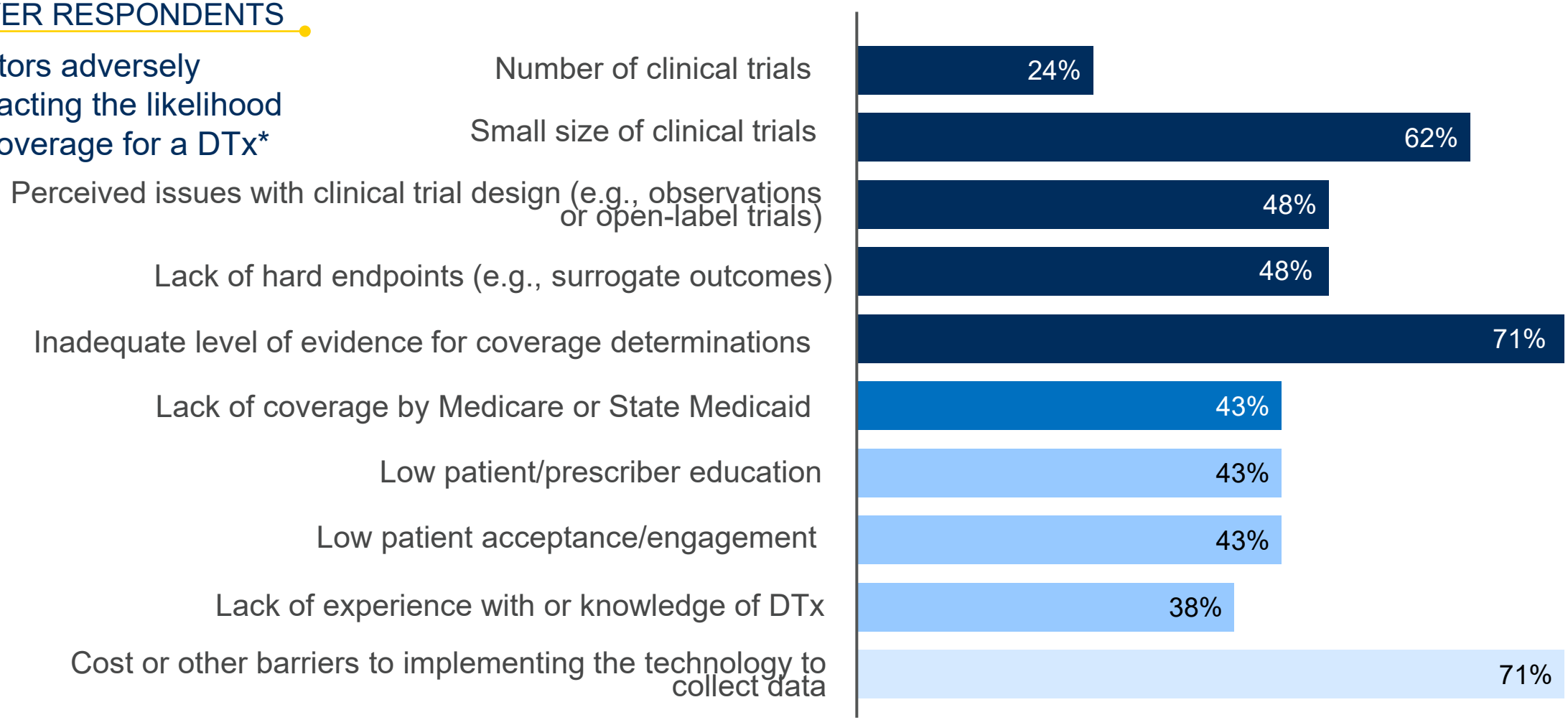


AMCP/Cyan Health Survey: August 2021 N=23 Payer Respondents
DTx = digital therapeutics.

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

PAYER RESPONDENTS

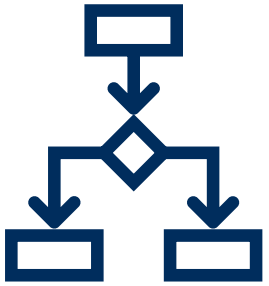
Factors adversely impacting the likelihood of coverage for a DTx*



AMCP/Cyan Health Survey: August 2021 N=21 Payer Respondents
*This was a “select all that apply” question.

What we need:

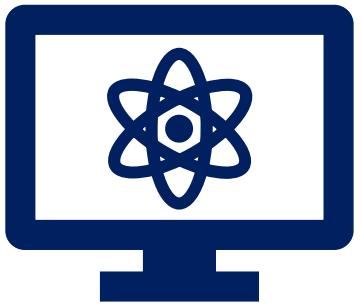
More and better evidence



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

DIGITAL MEDICINE SOCIETY

hih

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

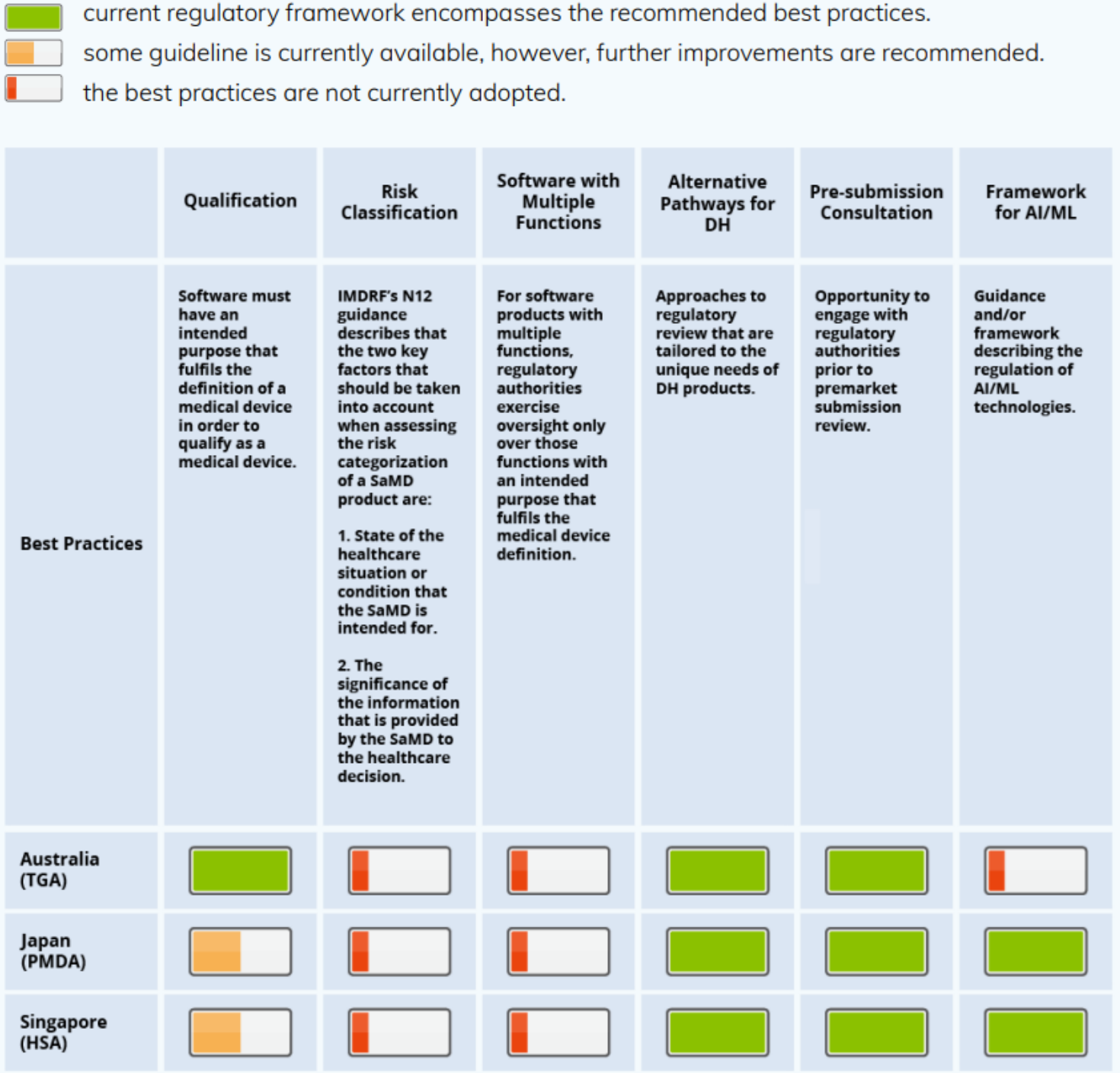
European digital health regulatory landscape is soaring

- 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

Source: PalmHealth.co

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



Source: APACmed

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