

# The Need for Transitional Coverage for Emerging Technologies

Stanford Byers Center for Biodesign &  
Duke-Margolis Center for Health Policy

March 28, 2022

12:00-2:00 pm ET/ 9:00-11:00 am PT

# The Stanford Biodesign Innovation Policy Program

**Josh Makower, MD**

Director & Co-Founder, Stanford Byers Center for Biodesign  
Professor of Medicine & Bioengineering, Stanford University

# A New **Policy** Program Within Biodesign...

- New Innovation Policy **Research** Organization in Biodesign
  - Focused on current policy issues
  - Stakeholder outreach for priority setting
- New 2-Year Policy **Fellowship**
  - 1 year in Biodesign, 1 year in Washington, DC / other
  - Fellows exposed to innovation & frontline policy issues
  - Applications being accepted Q3 2022 for Q3 2023 enrollment
- New Convening **Events / Engagement**
  - Events like this webinar
  - Partnering with government agencies & other leading research/policy organizations

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  - Develops and supports innovative educational and training opportunities in health policy across the educational continuum

## Priority Domains

### Healthcare Transformation

Identifying best practices in major payment and care delivery reforms at the practice, state, and national level.

### Biomedical Innovation

Improving the regulatory process of medical product development and demonstration of approved product's value in the real world.

### Education and Workforce

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# Current Status and Outlook for Medicare Policies Affecting Breakthrough Devices

*Mark McClellan, MD, Duke-Margolis Center for Health Policy*

# Factors Affecting Uptake of Breakthrough Devices for Medicare Beneficiaries *After* FDA Approval

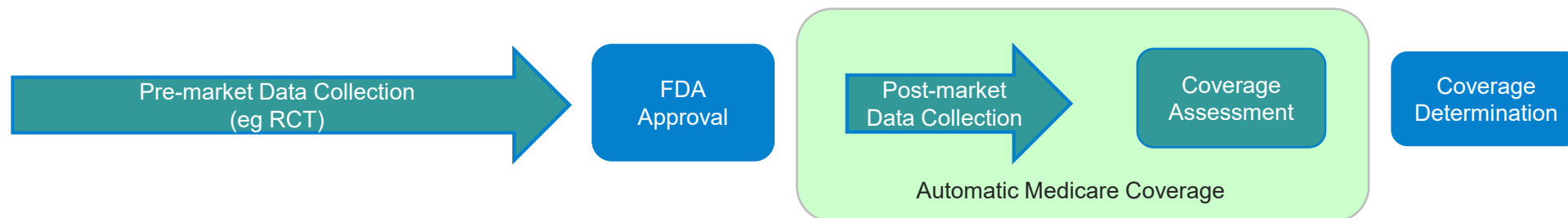
- **Coding:** Assignment of specific codes to replace provisional codes for reliable billing (AMA CPT process) takes time and requires evidence on clinical use.
- **Coverage:** FDA-approved products can be billed on an individual claim basis, but “local” coverage decisions may be unclear and (infrequently but importantly) the need for a National Coverage Determination may result in delays.
- **Payment:** New technology add-on payment (NTAP) may be needed for costly devices used in inpatient setting or other bundled payment programs.
- **Evidence:** Breakthrough devices are approved with limited evidence on long term outcomes and durability and other evidence that informs patient selection and treatment success in real-world practice, and often with limited evidence on Medicare beneficiaries.
- **Confidence:** Beneficiaries and their clinicians need evidence and experience to make confident decisions about using a new device.
- **Appropriateness and value:** Medicare services are increasingly delivered through Medicare Advantage plans and through accountable providers and specialists in Traditional Medicare. There is increasing attention to appropriate use based on concerns about treatments that are high cost, relative to available evidence of their benefits.

# Medicare Coverage for Breakthrough Devices Today

- As of September 2020, 16 devices with breakthrough designation had reached FDA approval.
  - 10 fell under a Medicare benefit category, with a subset of these 10 requiring coverage assessments.
- A Medicare coverage assessment determines whether a technology is “reasonable and necessary” (R&N) for beneficiaries, based on whether the device results in improved outcomes for Medicare beneficiaries.
- Breakthrough devices may face uncertainties and delays in achieving consistent national coverage:
  - FDA-cleared items and services are eligible for payment on an individual claim determination basis, but this process may result in payment delays and inconsistencies.
  - Medicare’s local contractors (MACs) may use provisional codes and set payment levels for products not covered through bundled payments like DRGs for inpatient devices, but these policies can be inconsistent.
  - If required, a National Coverage Assessment process has a statutorily defined timeline of 9-12 months.
- For new technologies with insufficient evidence to satisfy the “reasonable and necessary” determination, Coverage with Evidence Development has been used to provide access as part of a national coverage assessment.
  - The infrastructure and systems to collect data and develop needed evidence may be limited, especially in the absence of advance planning.

# Proposals to Expedite Coverage for Breakthrough Devices

- **Medicare Coverage of Innovative Technology (MCIT)** was originally proposed in September 2020, delayed and repealed November 2021.
- **21st Century Cures Act (Cures 2.0)** proposed a similar transitional process for automatic coverage for all breakthrough devices with provisional codes and payment.
- **Concerns about MCIT**
  - Limited evidence: Clinical trial studies used for FDA approval for breakthrough devices are not required to enroll Medicare patients, so that a breakthrough device could be used in the Medicare population despite limited evidence on safety and effectiveness
  - Interim coverage under MCIT did not have clear process for manufactures to get CMS guidance on the additional evidence needed for “reasonable and necessary” determination for long term Medicare coverage
- **Transitional Coverage for Emerging Technologies:** proposal expected Fall 2022 that aims to address MCIT concerns while creating faster and more certain coverage breakthrough devices.



# Meeting Agenda

- **Lee Fleisher, CMO and Director, Center for Clinical Standards and Quality, Centers for Medicare and Medicaid Services** *(12:10 pm ET / 9:10 am PT)*
- **Session 1: Medicare Coverage of Innovative Technology Survey Results:** Share research findings that support a well-designed coverage pathway that focuses both on coverage and evidence development *(12:30 pm ET/ 9:30 am PT)*
- **Session 2: Potential Path Forward for Transitional Coverage:** Discuss the key elements necessary to make a successful transitional coverage pathway for breakthrough devices *(12:50 pm ET/9:50 am PT)*
- **Session 3: Transitional Coverage Pathway in Practice:** Identify the operational elements of a pathway that would ensure transitional coverage translates into improved patient access in real-world settings *(1:25 pm ET/10:25 am PT)*

# Lee Fleisher, MD

*Chief Medical Officer and Director for the Center for Clinical Standards and Quality, CMS*

*12:10 – 12:30pm ET / 9:10 – 9:30am PT*

# Disclaimer

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This presentation is a general summary that explains certain aspects of the Medicare Program, but is not a legal document. The official Medicare Program provisions are contained in the relevant laws, regulations, and rulings. Medicare policy changes frequently, and links to the source documents have been provided within the document for your reference

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**No financial conflicts to disclose**

# CMS Strategic Pillars

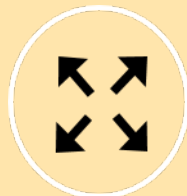
## ADVANCE EQUITY

Advance health equity by addressing the health disparities that underlie our health system



## EXPAND ACCESS

Build on the Affordable Care Act and expand access to quality, affordable health coverage and care



## ENGAGE PARTNERS

Engage our partners and the communities we serve throughout the policymaking and implementation process



## DRIVE INNOVATION

Drive Innovation to tackle our health system challenges and promote value-based, person-centered care



## PROTECT PROGRAMS

Protect our programs' sustainability for future generations by serving as a responsible steward of public funds



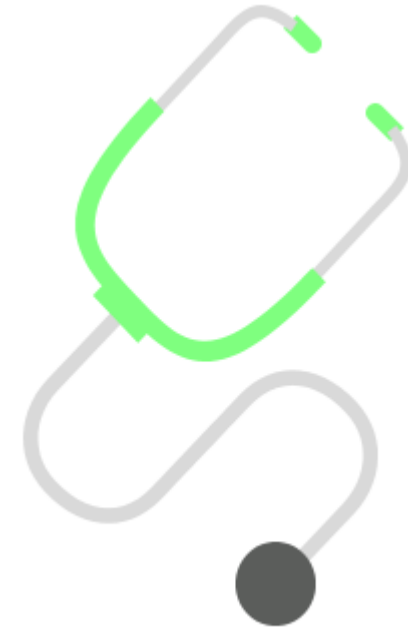
## FOSTER EXCELLENCE

Foster a positive and inclusive workplace and workforce, and promote excellence in all aspects of CMS's operations



# CMS Mission: Promoting Evidence-based Care

- Evidence-based coverage underpins the HHS / CMS value mission
- CMS is uniquely positioned to establish evidence-based care standards
- CMS may extend coverage to an item or service that is considered “reasonable and necessary” as defined under the Social Security Act
- CMS is evaluating items and services to ensure they are 1) safe and effective, 2) not experimental or investigational, and 3) appropriate for Medicare beneficiaries



# CMS Coverage Options for both Routine and Emerging (Breakthrough) Technologies

## National Level

### National Coverage Determination (NCDs) +/-

#### Coverage with Evidence Development

- 3 - 4 completed annually, on average
- Timing driven by available resources, priorities, and external factors
- Finalized 9 months after opening
- Current waitlist

## Local (MAC) Level

### Local Coverage Determination (LCDs)

- 37 unique LCDs annually, on average
- May vary by jurisdiction, less so for lab tests and durable medical equipment
- Effective ~ 9 months after opening

### Individual Claim Determination

- No NCD or LCD
- Coverage based on individualized MAC assessment

# Current State: Coverage Challenges with Emerging Technologies

- National Coverage Determinations establish conditions of coverage for emerging, high impact technologies. Anyone can ask to open an NCD.
- Benefit Categories
  - Medicare is a defined benefit program (BCD)
  - Coding
- With respect to coverage decisions
  - Evidence of Benefit
    - Strength of evidence
  - Risk of Harm
    - Low risk
    - High risk
    - Adequate evidence to define risk including patient, provider, facility characteristics

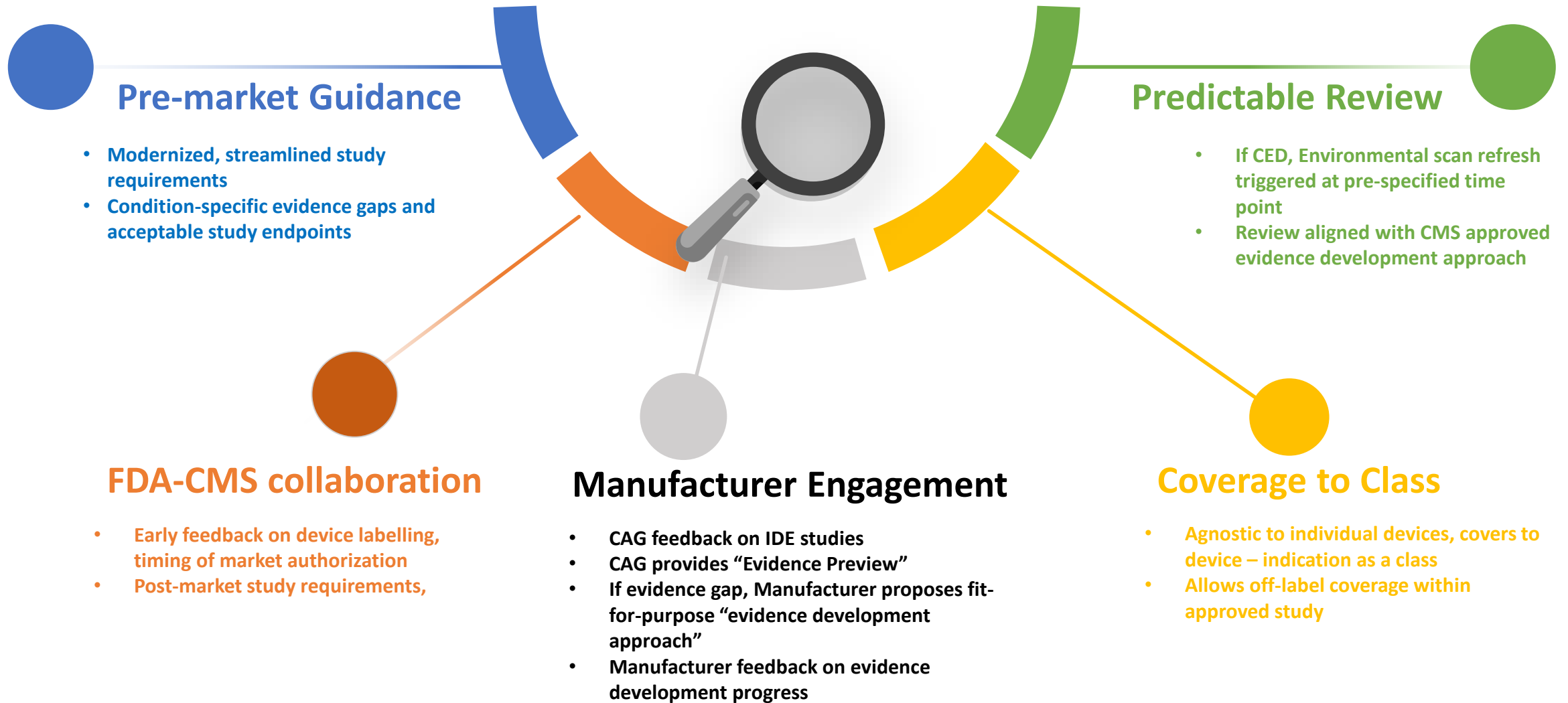
## Future State: Next Steps

- CMS wants to engage with all stakeholders to help shape the future state of covering emerging technologies
- Held a listening session in February 17, 2022
- Next listening session is March 31, 2022

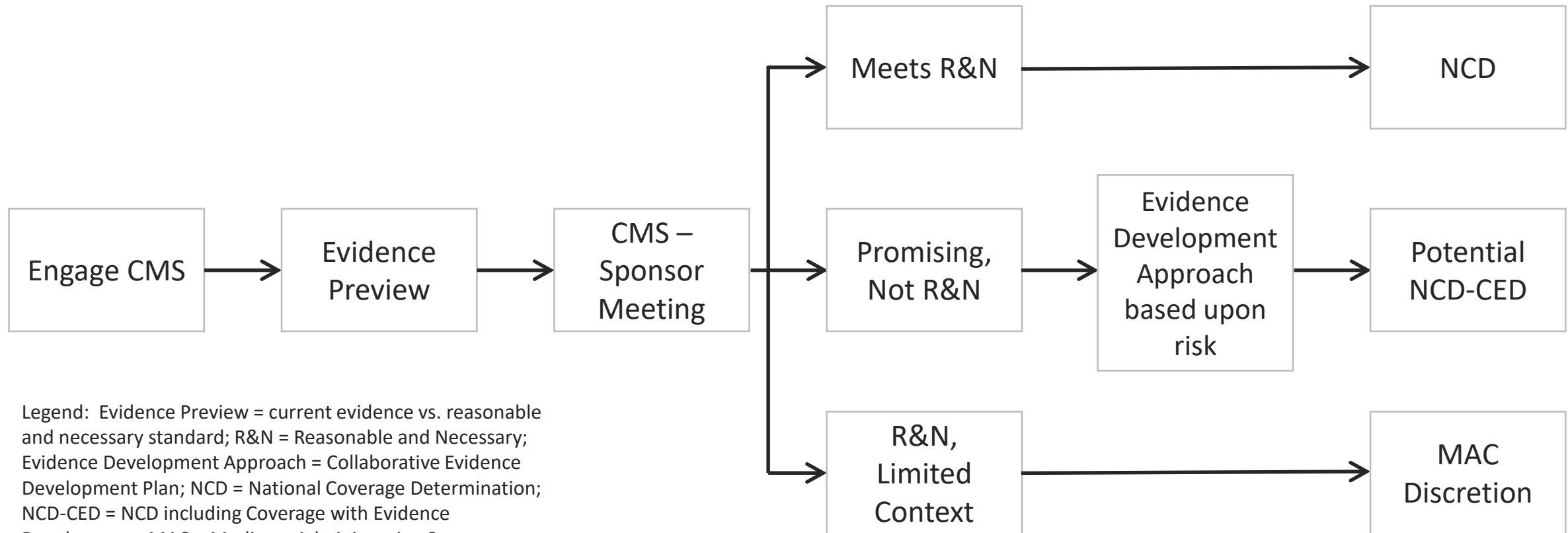
# Future State: Early Considerations

- CMS is in the initial stages of considering new coverage approaches for emerging technologies
- Pre-Coverage Decision
  - Evidence Preview Pilot Program
    - National Coverage Analysis is a public process
    - Snapshot evidence preview
    - Defines any presumptive evidence gaps
  - Environmental Scan
    - Open and transparent systematic literature review
    - Standardized evidence grading
    - Risk of Bias Assessment
    - Applicability Assessment
- Potential Coverage Pathways
  - Evidence Development Approach
    - Manufacturer proposes evidence development approach
    - Manufacturer proposes beneficiary protections

# One pathway based upon feedback



# Future State for Emerging Technologies: Mapping a Potential Coverage Process



Legend: Evidence Preview = current evidence vs. reasonable and necessary standard; R&N = Reasonable and Necessary; Evidence Development Approach = Collaborative Evidence Development Plan; NCD = National Coverage Determination; NCD-CED = NCD including Coverage with Evidence Development; MAC = Medicare Administrative Contractor.

# Thank you!

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Lee Fleisher, M.D.

[Lee.Fleisher@cms.hhs.gov](mailto:Lee.Fleisher@cms.hhs.gov)

# Medicare Coverage of Innovative Technology Survey Results

*Sandra Ruggles, PhD, Assistant Director Innovation Fellowship,  
Stanford Byers Center for Biodesign*

*12:30 – 12:50pm ET / 9:30 – 9:50am PT*

# The Need for Accelerated Medicare Coverage of Innovative Technologies

## Impact on Patient Access and the Innovation Ecosystem

Sandra Waugh Ruggles, PhD, Juliana Perl, Zach Sexton, Kevin Shulman, MD, Josh Makower, MD  
*Health Management, Policy and Innovation* ([www.HMPI.org](http://www.HMPI.org)), Volume 7, Issue 1.

# Background

MCIT was proposed to accelerate patient access to breakthrough technology.

Anecdotally, the challenges of establishing reimbursement derail early-stage technology development and fundraising.



# Scope

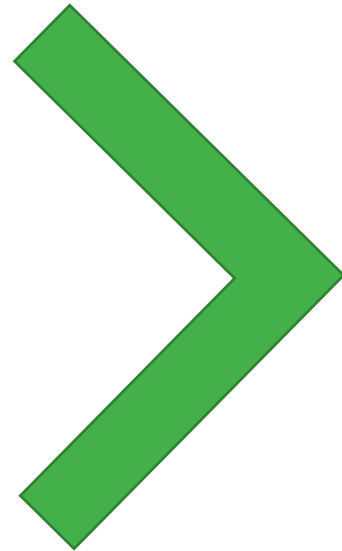
Solicit input from industry professionals who are experienced at developing novel technology.

Address key questions:

- Does a quantitative assessment validate anecdotal experiences?
- What is the impact of current reimbursement processes on patient access to new technology?
- How well are current pathways meeting patient need?
- How would an MCIT-like program impact development of novel technology?

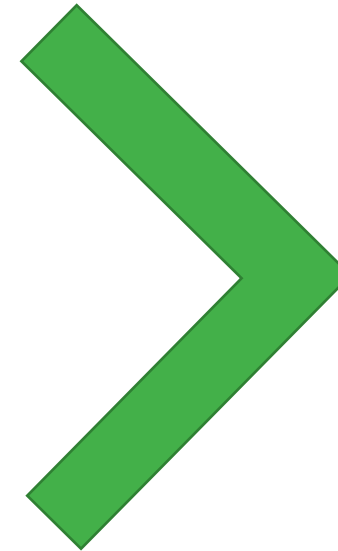
# Respondents reflect the innovation ecosystem

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**336**  
responses

*Respondents screened for  
expertise in reimbursement*



**253**  
innovators

**83**  
healthcare investors

*Respondents selected their  
professional focus*

# Respondent Demographics



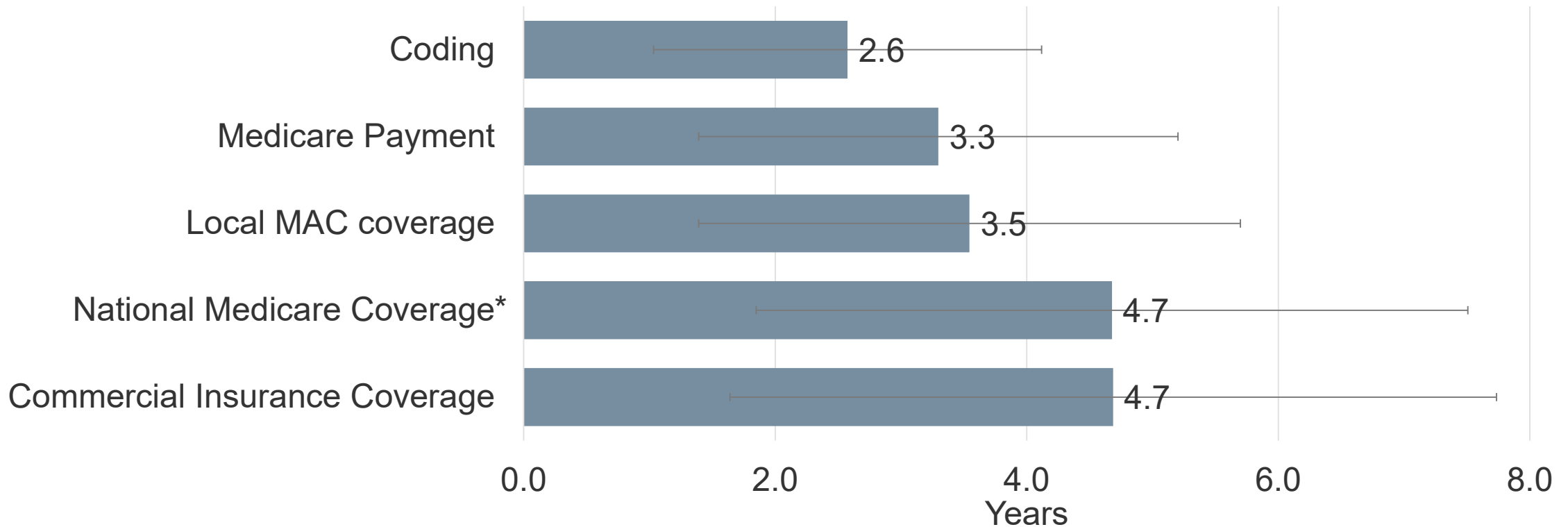
- Primarily reimbursement (24%) and executive leadership (60%) roles.
- Primarily from companies of <50 employees (57%) or 50 to 500 employees (21%).
- Majority with over 10 years experience in healthtech (86%), and experience in an average of 3.1 clinical areas.



- On average, \$1.4 B dedicated to healthcare investing.
- Majority (55%) were investing funds of \$100MM to \$500MM.
- For 41% of investors, medical device and diagnostics accounted for the majority of their investments.

# Extended and variable timelines to reimbursement delay patient access

Time to reimbursement milestones following FDA authorization

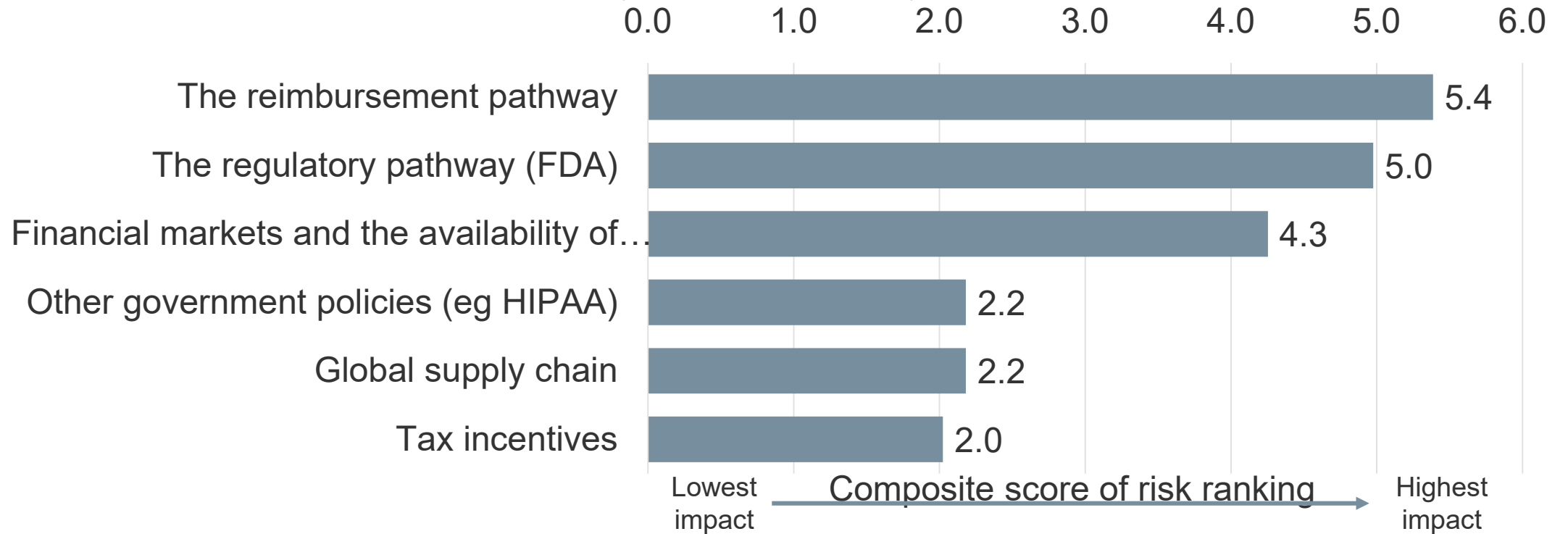


\* The survey used the phrase “national Medicare coverage” to encompass a National Coverage Determination (NCD) and nationwide coverage through the accumulation of local MAC coverage decisions.

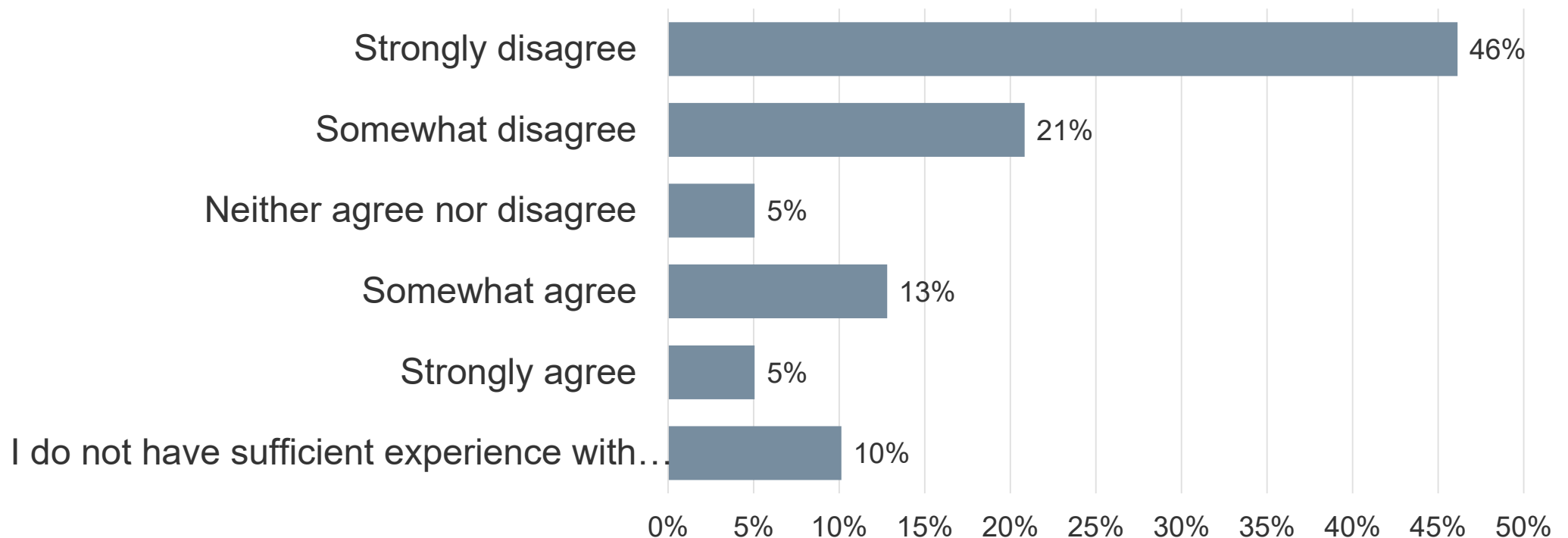
# Reimbursement is the top external factor for investors

Importance of external factors on the decision to invest or not invest in a healthcare company

(Composite score, N=83)



# Does the existing process provide timely patient access for novel medical technologies?



Innovator and investor respondents were asked to respond to the question “Do you agree or disagree with the following statement? The existing parallel review process with FDA and the CED pathway are sufficient to provide timely patient access for novel medical technologies.”

# Evident frustration about the post-authorization path to reimbursement

“challenging”

*“Without clear guidance and agreements early on, the system penalizes innovation and rewards incremental changes. It is hard to fund start-ups with breakthrough technologies because of the reimbursement challenges.”*

“circular”

*“It is discouraging that the evidence collected for FDA approval counts so little for the reimbursement decisions. This is particularly true for orphan markets, and it means that patients often don't get access to important, breakthrough technologies.”*

“highly variable”

“unpredictable”

*“Part of the challenge is the lack of predictability in the timeline and process. If it's long, but predictable, that timeline can be planned for. It's the lack of transparency that is the issue.”*

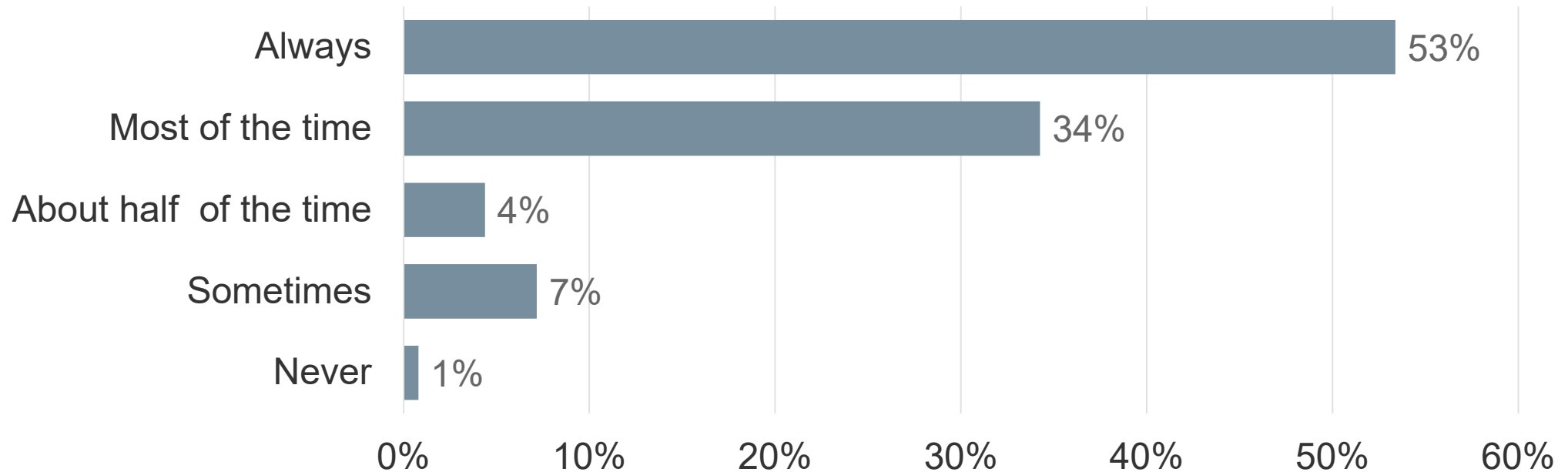
“too long”

# A desire for transparency and predictability

- *“We need the FDA and CMS to work together to align on evidence requirements and bring clarity to what is currently a very confusing mix of rules and regulations.”*
- *“The MCIT rule would provide significant clarity and timeline with an intermediate reimbursement to soften the impact of the multi-year “valley of death” between regulatory approval/clearance and established coverage.”*
- *“CMS needs to move faster, be more transparent, predictable and responsive, and publish its decisions publicly so innovators can more accurately predict how their product will be reimbursed.”*

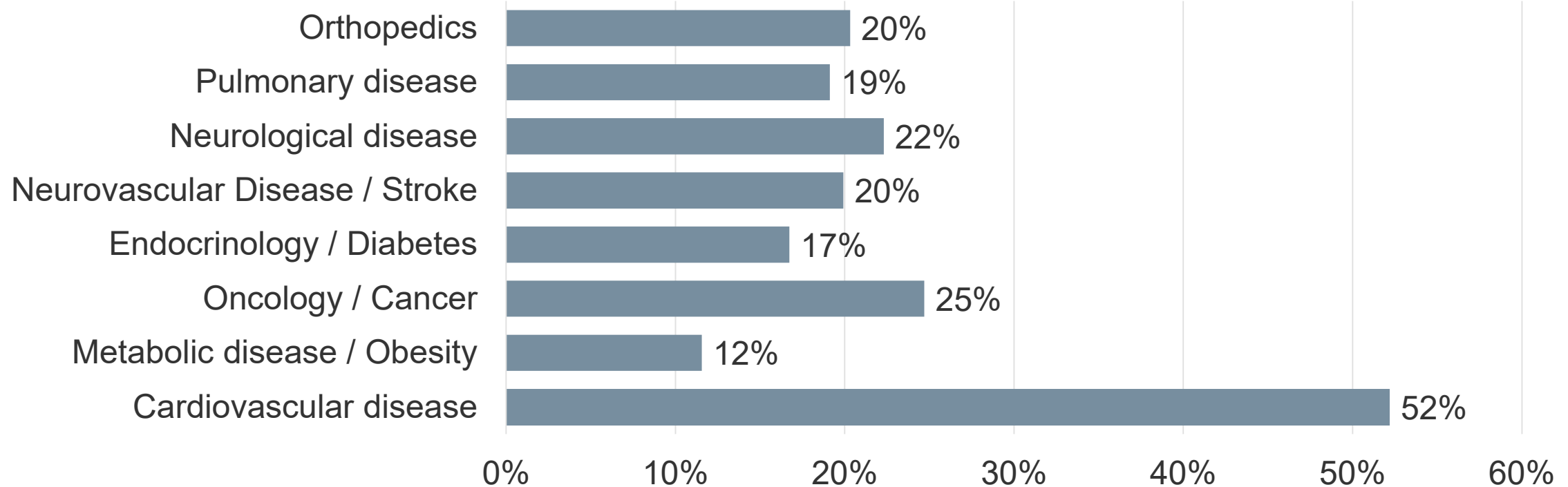
# Post-authorization clinical evidence collection is commonplace

Frequency of real-world evidence collection following FDA authorization  
(% of respondents, N=253)



# An MCIT-like program stimulates innovators to take on breakthrough product development

Innovators experienced and likely to develop novel and breakthrough products in specific clinical areas  
(% of respondents, N=253)



# Key Learnings and Insights

- Survey respondents stated that it takes an average of 4.7 years and up to 8 years **after** FDA authorization for nationwide coding, coverage and payment.
- Innovators are frustrated with the current pathways to reimbursement.
- Respondents do not believe that current pathways are sufficient to ensure patient access to new technology.
- Collection of post-authorization clinical evidence is common.
- An MCIT-like program stimulates innovator interest in breakthrough products in areas important for Medicare beneficiaries.

# Potential Path Forward for Transitional Coverage for Emerging Technologies

*Mark McClellan, MD, Director, Duke-Margolis Center for Health Policy*

*12:50 – 1:25pm ET / 9:50 – 10:25am PT*

# Transitional Pathway Proposals: Where are we now?

- **CMS suspended then repealed the MCIT proposal in November 2021**, citing the pathway had limited ability for CMS to ensure safety of Medicare beneficiaries:
  - Limited ability of CMS to restrict coverage in the event that a device posed a safety concern for Medicare beneficiaries.
  - MCIT lacked requirements and enforcement mechanisms for stakeholders to develop evidence during the breakthrough coverage period.
  - MCIT coverage not available to subsequent market entrants, potentially leading to inconsistent coverage and disincentivizing innovation from potentially better devices.
- In early 2022, CMS announced a **new initiative called Transitional Coverage for Emerging Technologies**, a potential replacement for MCIT.

# Themes from MCIT and TCET Comments

- The dialogue between stakeholders and CMS throughout the evolving transitional coverage proposals highlights several overarching objectives for the pathway:
  - Need for more timely and predictable coverage, along with coding and payment, for breakthrough devices.
  - Steps to ensure safety of Medicare beneficiaries based on evidence at approval.
  - Clearer guidance from CMS to manufacturers on pre- and post-market evidence generation relevant to Medicare beneficiaries.
  - Clearer guidance from CMS for a clear, efficient path to a long-term “reasonable and necessary” determination for Medicare coverage, including conditions for ending data collection.
  - Assistance from CMS on coordinating coding and payment processes, along with coverage, to secure reliable and appropriate Medicare reimbursement.

# What could TCET look like?

## Concerns with MCIT

## Possible Solutions

Limited ability of CMS to ensure safety of Medicare beneficiaries

- Early manufacturer engagement with CMS for guidance on key evidence questions for Medicare beneficiaries and their clinicians
- CMS retains authority to modify or rescind national coverage during the expedited pathway process if safety concerns are found.

May provide coverage with inadequate supporting data on benefits for Medicare populations.

- Early engagement and planning between CMS, FDA, manufacturers, clinicians and other stakeholders during pre-approval process to identify and address key gaps in evidence.

Voluntary data collection can lead to insufficient evidence for permanent coverage determinations.

- Plan for evidence development for breakthrough devices that have significant evidence gaps, using Coverage for Evidence Development or other evidence generation (e.g. continue follow-up from pivotal clinical trials), with advance planning to facilitate more efficient and less burdensome approaches

Inconsistent coverage for subsequent market entrants, including better or less costly devices, reducing access and discouraging innovation.

- Consistent with past Medicare coverage determinations, coverage for a breakthrough device includes relevant follow on and iterative devices.

Unclear path to minimize gaps in access from coding and payment.

- Coordination with CM Technology Coding and Pricing Group, and other entities, to take steps to address coding and payment issues prior to approval.

# Framework for appropriate use of Breakthrough Devices

A standardized, operational framework with a predictable timeline to conduct evidence reviews, develop benefit category determinations, establish provisional and permanent codes, and payment.

CMS engagement with FDA, sponsor,  
other stakeholders

FDA Approval  
+ TCET

Ongoing engagement between  
CMS and stakeholders

Final  
Coverage

Apply to expedited  
coverage pathway prior  
to FDA approval



Preliminary assessment  
of evidence and  
guidance on navigating  
coding and payment  
processes



Public comment and  
finalization of coverage  
policy, including  
postmarket evidence plan  
if significant evidence  
gaps for beneficiaries



Plan for timely analysis  
and completion of  
postmarket evidence,  
which may include  
clearly delineated CED

- [Duke-Margolis has previously published recommendations](#) for an operational framework for expedited coverage of breakthrough devices when the standard coverage process is not adequate for timely and appropriate access.
- This special coverage process will not be needed for all breakthrough devices. Most breakthrough devices to date have not experienced coverage issues because they are not relevant for the Medicare population, they may only need a determination of whether they fall under an existing benefit category, or they have an existing reimbursement pathway.

# Need for incremental additional resources at CMS

- FDA and NIH received substantial new resources with Cures 1.0, which (along with user fee resources) enables capacity for timely FDA engagement and action on breakthrough products.
- In contrast, CMS resources to support timely coverage decisions and reimbursement processes have *fallen* at the same time as the agency is facing a growing array of breakthrough products approved using expedited pathways.
- Additional funding and staff are needed to analyze new evidence, communicate with manufacturers and FDA, and carry out TCET expectations efficiently and effectively.
  - Additional medical officers with subject matter expertise
  - Additional engagement in horizon scanning and with experts and beneficiaries
  - Dedicated appropriations would be relatively modest, since TCET is likely to be needed only for a minority of breakthrough products

# Panel Discussion



Dirksen Lehman  
*Edwards Lifesciences*



Josh Makower  
*Stanford Byers Center for  
Biodesign*



Parashar Patel  
*ViewRay*



Kevin Schulman  
*Stanford Graduate School of  
Business*

- What are the key elements of an expedited pathway to ensure both quicker access and safe, appropriate use of breakthrough devices?
- What are some of the features in the current national and local coverage processes that work well and can be applied to an expedited coverage pathway for breakthrough devices? What are some features that could be reevaluated?

# Dirksen Lehman, JD

*Corporate Vice President, Public Affairs, Edwards Lifesciences*

# Josh Makower, MD

*Director & Co-founder, Stanford Byers Center for Biodesign*

# Disclosures

- Joshua Makower, MD, is an endowed professor derived from funds sourced from an endowment grant that was originally donated to Stanford Biodesign from Guidant Corporation and later named by Boston Scientific, Inc.
- Dr. Makower is also a compensated consultant and/or advisor to, on the board of, a shareholder of and/or founder of New Enterprise Associates, ExploraMed Development, Coravin, Willow Innovations, DOTS Devices, Eargo, Setpoint Medical, Allay Therapeutics, Intrinsic Therapeutics, Revelle Aesthetics, Moximed, Magenta Medical, and Lungpacer Medical.

# The Existing System Does Not Work For Patients, Payers or the Innovation Ecosystem

- As survey respondents stated, **4.7 years on average and up to 8 years** for nationwide coding, coverage and payment is too long.
  - These delays not only impact patients but also increase costs, which flow through the entire system
- Coding, coverage, payment for novel health technologies is mired by **challenging opaque processes** (AMA, Private Payers, MACs)
- **Investors are discouraged** from allocating dollars towards important, but difficult, clinical areas
  - The pace and cycle of innovation is slowed by delays in the system
- Poor feedback and alignment on best **real-world evidence** (RWE) methods
- Today even after coding, coverage and payment is established, **natural systemic regulators remain**

# A Strong Transitional Coverage Pathway Would Make a Positive Impact

- The pathway should be **voluntary** and provide for early confidence & **predictability** (as early as prior to FDA pivotal study design)
- Transitional coverage in exchange for **real-world evidence** collection with pre-agreed outcome performance criteria established
  - These criteria must be **transparent and fair**, otherwise the pathway will be under-utilized like the other CED programs currently established
  - CMS needs to ensure the MACs are on board
  - Follow-on tech improvements should be covered/included
- **Pathway to permanent** coding, coverage & payment needed
- **Pathway for removal** of technologies, if necessary for beneficiary protections
- **Adequately resource CMS** to conduct and scale the program

# Parashar Patel

*Senior Vice President Government Affairs & Market Access, ViewRay*

# Improving Medicare Coverage

## Public Webinar - The Need for Transitional Coverage for Emerging Technologies (TCET)

Stanford Byers Center for Biodesign & Duke-Margolis Center for Health Policy

March 28th, 2022

Parashar Patel

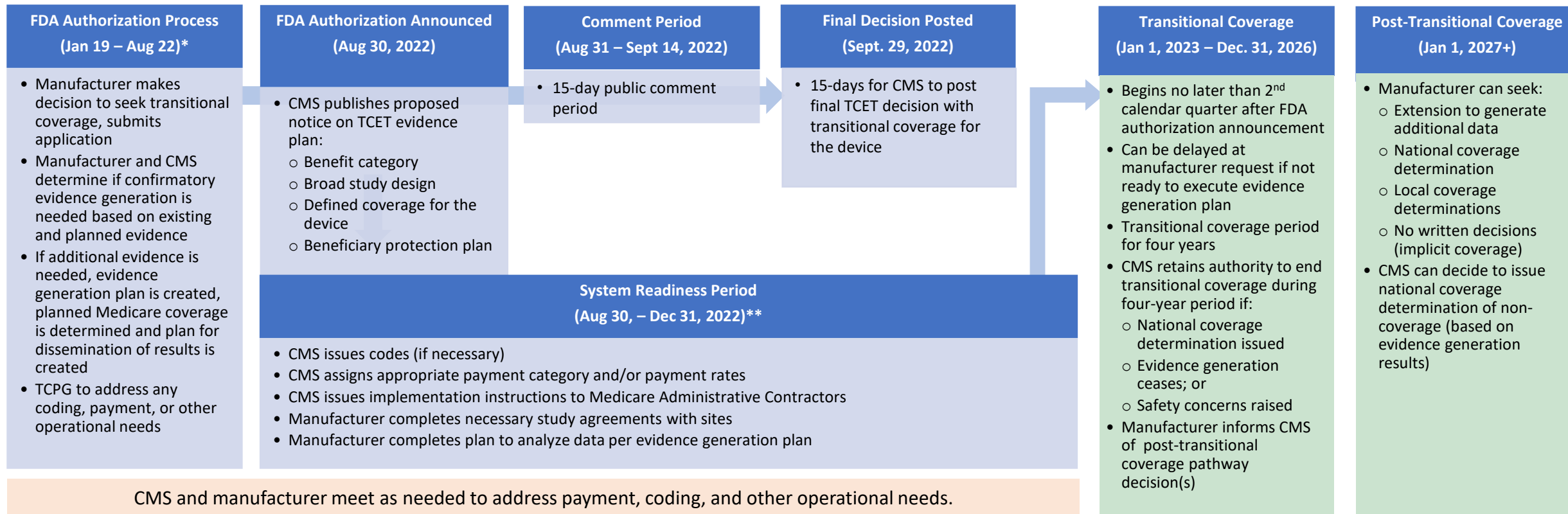
# Participants



# Executive Summary

- Shared goals:
  - An expeditious and predictable process to cover new, innovative devices that benefit Medicare patients based on scientifically sound clinical evidence and with appropriate safeguards
- Conceptual framework for coverage:
  - Early engagement between manufacturer and CMS to identify evidence needs
  - Aligned plan for evidence generation in the Medicare population
  - Focus on beneficiary protections and appropriate safeguards
  - Opportunity for public comment
  - System readiness time frame (coding, payment, carrier instructions, etc.)
  - Addresses follow-on devices

# Program Overview



- Example assumes CMS and manufacturer reach agreement on evidence generation plan prior to FDA authorization. If agreement reached post-FDA authorization, proposed decision posted on date of agreement and timeline shifts accordingly.

\* Dates serve as example only. FDA review times will vary.

\*\* Dates serve as example only. System readiness period may be up to 180 days. However, length of time may vary based on operational needs.

# Kevin Schulman, MD

*Professor of Medicine, CERC, Stanford University School of Medicine*

# Supporting Medical Device Innovation

MARCH 28, 2022

Kevin A. Schulman, MD

Professor of Medicine

Clinical Excellence Research Center

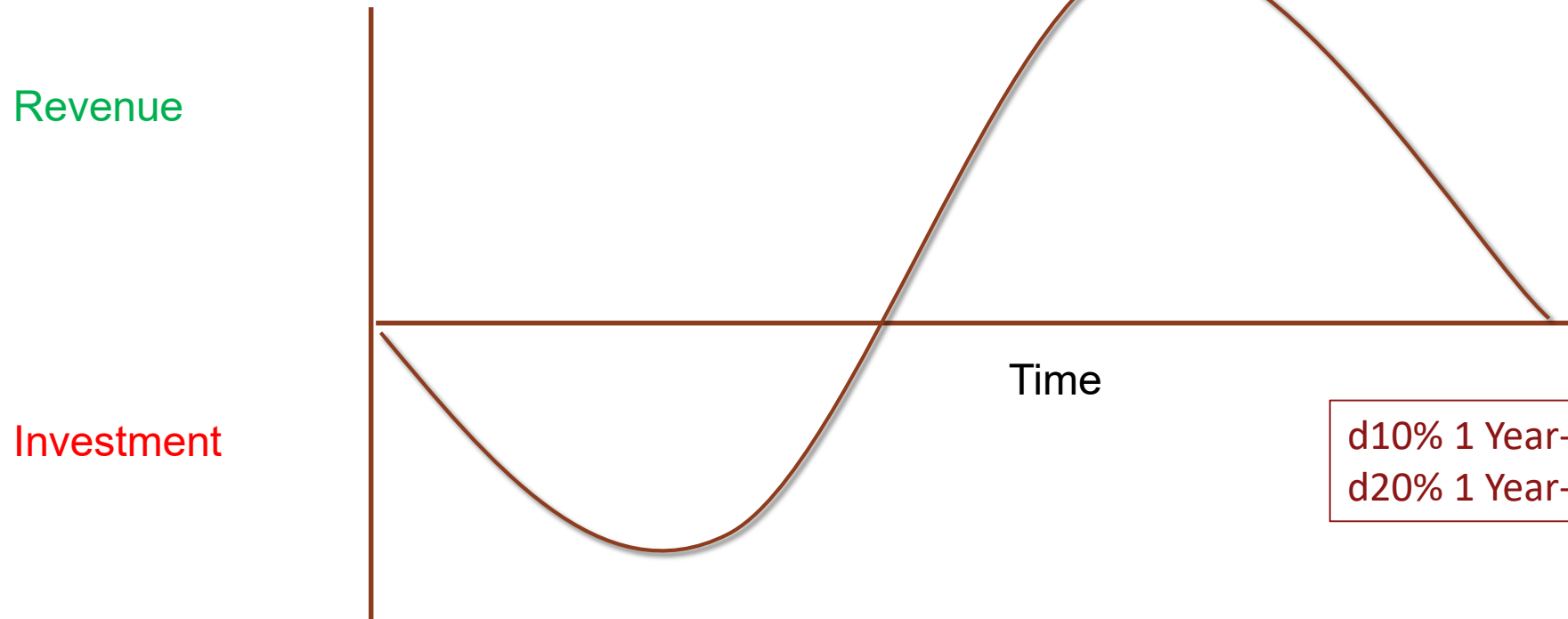
Department of Medicine

Professor of Economics, Graduate School of Business

Stanford University

# The Economics of Device Development

- NPV
- Discount Rate (d)
  - Clinical Risk
  - Business Risk
  - Reimbursement Risk
- Time:  $(1+d)^t$



d10% 1 Year-19% decrease  
d20% 1 Year-56% decrease

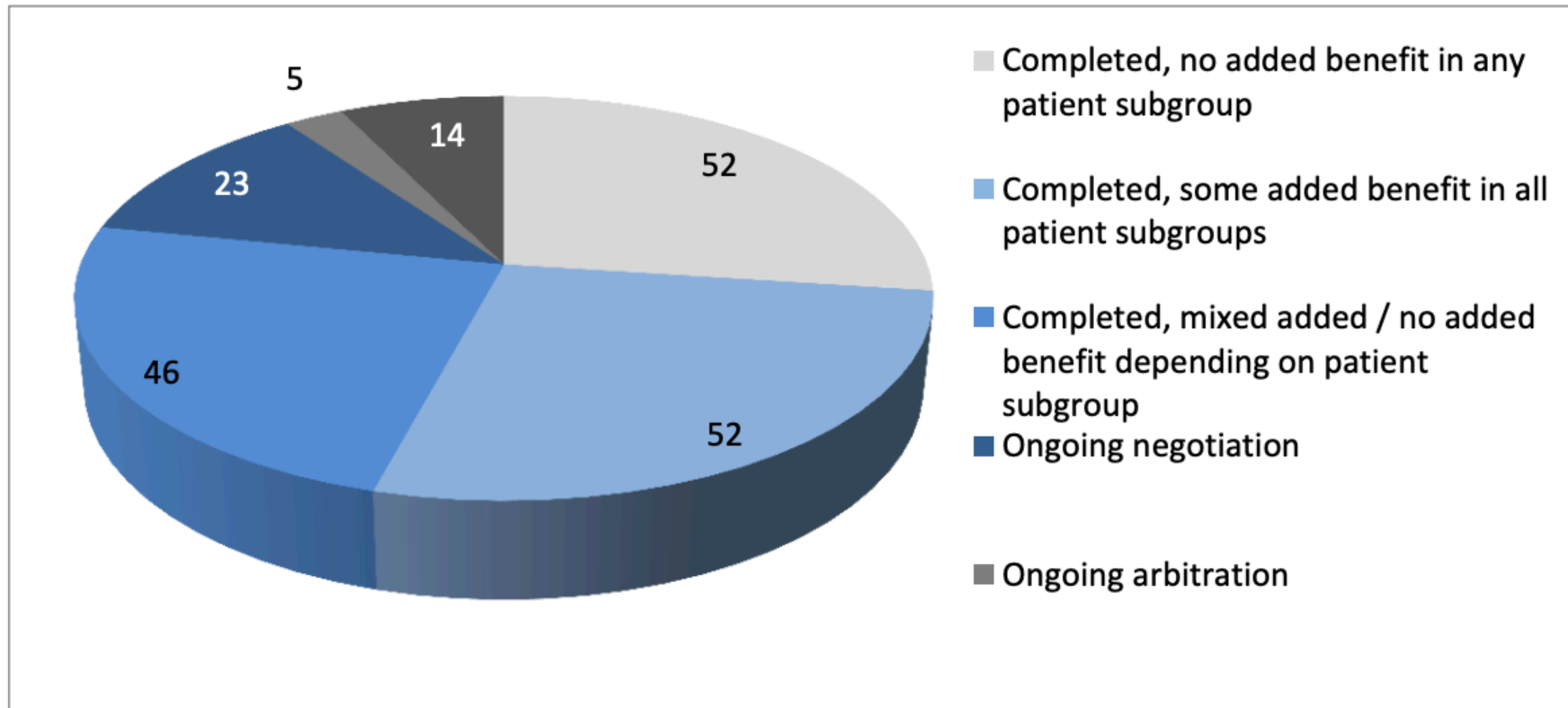
# (Coverage With) Evidence Development



- What are the side effects of the vaccine?
- How long does immunity last? In which sub-population?
- Can I mix vaccine manufacturers?
- What happens if I get COVID after vaccination?

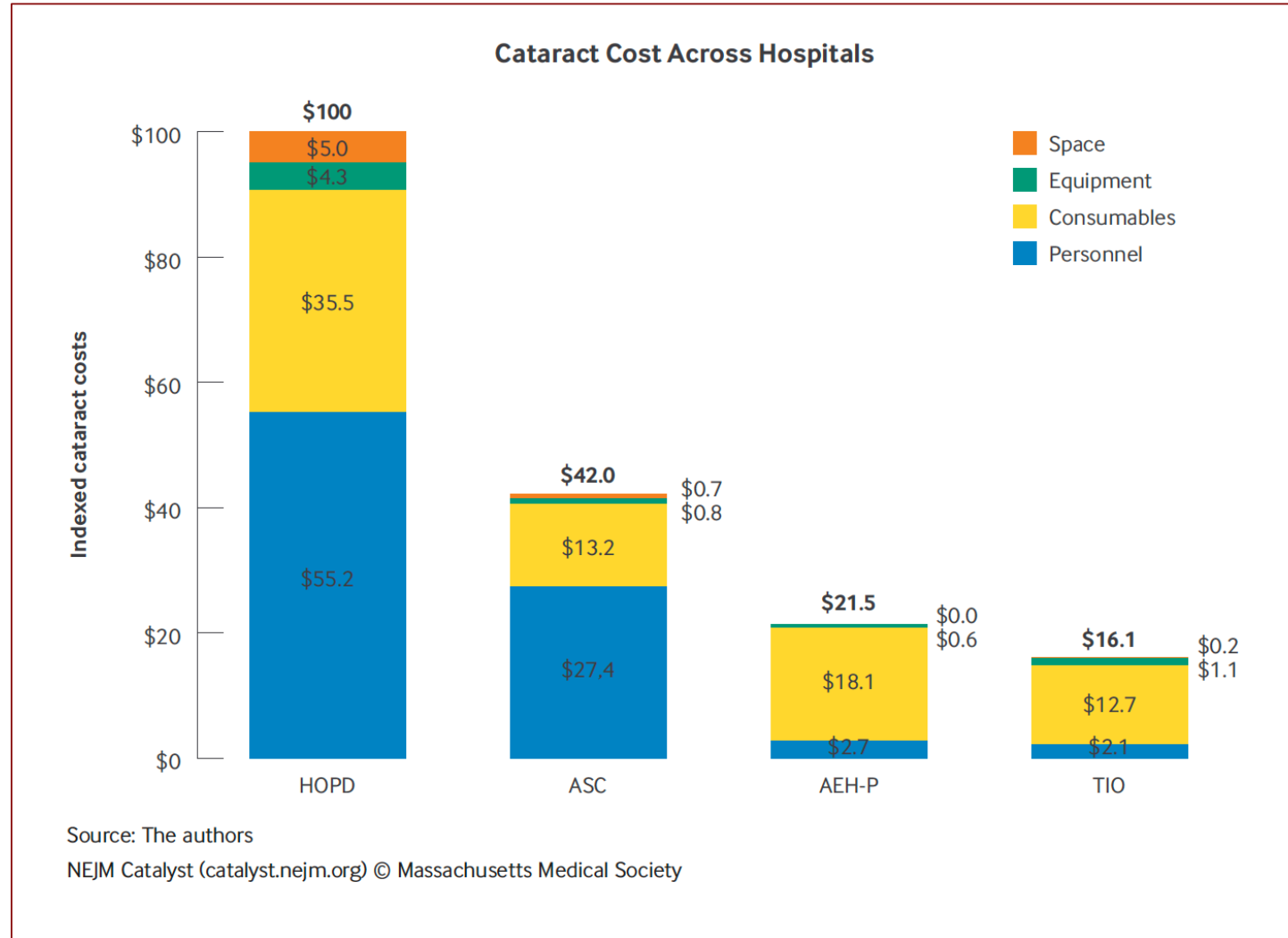
# Results from Germany

**Figure 1. Status of price negotiations and results of G-BA assessment for completed negotiations, per 15 August 2017**



Source: von Stackelberg et al, 2017

# Reverse Innovation



**Volume:**

**AEH-P  
25,826**

**TIO  
12,091**

# Panel Discussion



Dirksen Lehman  
*Edwards Lifesciences*



Josh Makower  
*Stanford Byers Center for  
Biodesign*



Parashar Patel  
*ViewRay*



Kevin Schulman  
*Stanford Graduate School  
of Business*

- What are the key elements of an expedited pathway to ensure both quicker access and safe, appropriate use of breakthrough devices?
- What are some of the features in in the current national and local coverage processes that work well and can be applied to an expedited coverage pathway for breakthrough devices? What are some features that could be reevaluated?

# Transitional Coverage Pathway in Practice

*Marianne Hamilton Lopez, Duke-Margolis Center for Health Policy*

*1:25 – 1:50pm ET / 10:25 – 10:50am PT*

# Coverage to Patient Access

- The proposed frameworks for transitional coverage emphasize steps to improve timely access to breakthrough devices.
- Beyond coverage, there are other key processes that will support timely patient access:
  - Reimbursement
  - Post-market data collection
  - Stakeholder engagement and alignment

# Aligning Processes for Coding and Payment

- A expedited coverage process should facilitate a pathway to coding and payment to establish reimbursement
- Currently, processes to establish codes and associated payment for sites of service as well as providers is time consuming and involve many stakeholders, including those outside of CMS
  - CMS has addressed coding application cycles recently, as well as streamlined NTAP processes for breakthrough devices
  - Physician codes, established through the AMA, if designated as emerging technology codes can be a barrier to financial access for providers

# Post-market Data Collection and Real-World Evidence

- Expedited approval pathways are built on the premise that there will be more evidence developed in the post-market phase.
  - Many FDA post-market authorization studies are not completed in a timely fashion.
- There is a need to efficiently and effectively collect evidence following FDA approval to demonstrate the value and clinical utility of breakthrough devices
  - In a value-based payment environment, coverage and reimbursement will not be sufficient to ensure market access for high cost devices with limited clinical evidence
- Current challenges with post-market evidence generation include:
  - Provider resource and administrative burden.
  - Capacity and quality to reliably collect patient reported outcomes.
  - In the absence of UDIs, how to identify reliably when a breakthrough device is used, for early post-market studies, safety surveillance, and other purposes.
- Opportunity to reevaluate and leverage pre-market evidence generation to incorporate RWE .

# Panel Discussion



Louise Guy  
*Argenta Advisors*



Michael Mack  
*Baylor Scott and White Health*



Joe Franklin  
*Verily*

- What are some of the operational elements needed to ensure that a new pathway to coverage leads to increased patient access to breakthrough devices?
- What are some of the ways in which we can improve the coding and payment processes to avoid gaps in access once there is Medicare coverage for a breakthrough device?
- What are other important challenges to patient access to these devices after a product receives coverage? What are some of the opportunities to improve patient access?

# Louise Guy

*President and Managing Partner, Argenta Advisors*

# The Need for Transitional Coverage for Emerging Technologies

Louise Guy  
March 28, 2022



# Transitional Coverage Pathway in Practice

Not surprisingly, there are significant **challenges**:

- “Coverage” does not **guarantee** adequate Payment for the device
  - DRG or APC assignment (Transparency in discussion with CMS for assignment related to pricing)
  - Payment and or pricing
- Applicable Coding will need to be already available
  - AMA/CPT involvement with procedure coding process
  - CAT-3, considered in the transitional process?
  - CAT-1 (new) only if peer review publications (5)
- How will hospital VAC committees evaluate the new Technology for adoption?
- Manufacturer has responsibilities
  - Update status to all parties
  - Outreach communication and strategy to educate each facility/provider
  - Seamless Plan for ensuring transition from clinical to commercial
- Should all parties come to the table for **transparent** pathway creation and implementation?
  - Manufacturer
  - CMS
  - FDA
  - Medical Society(ies)
  - Early Adopters



# Michael Mack, MD

*Medical Director, Cardiothoracic Surgery, Baylor Scott and White Health*

# Joe Franklin, JD, PhD

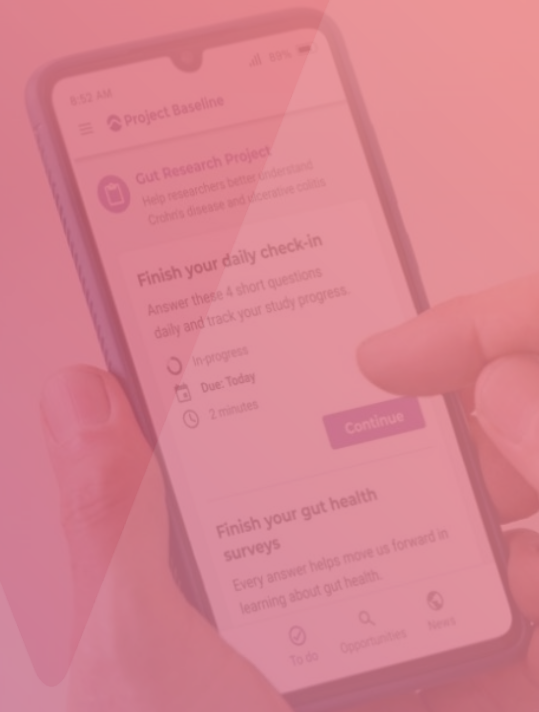
*Product Counsel, Verily Life Sciences*



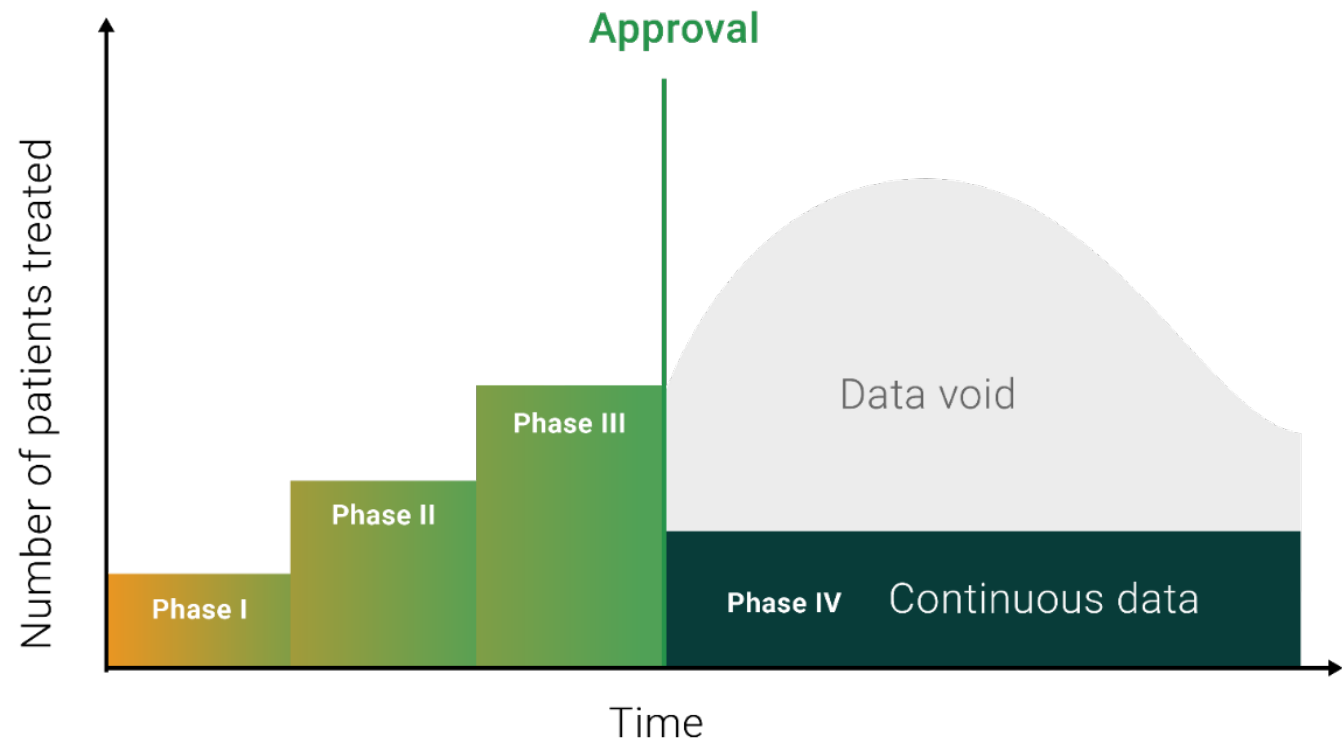
# Brief primer: Emerging clinical evidence generation tools

**Joe Franklin JD, PhD**  
**Product Counsel, Clinical Studies Platforms**  
**Verily Life Sciences**

March 2022

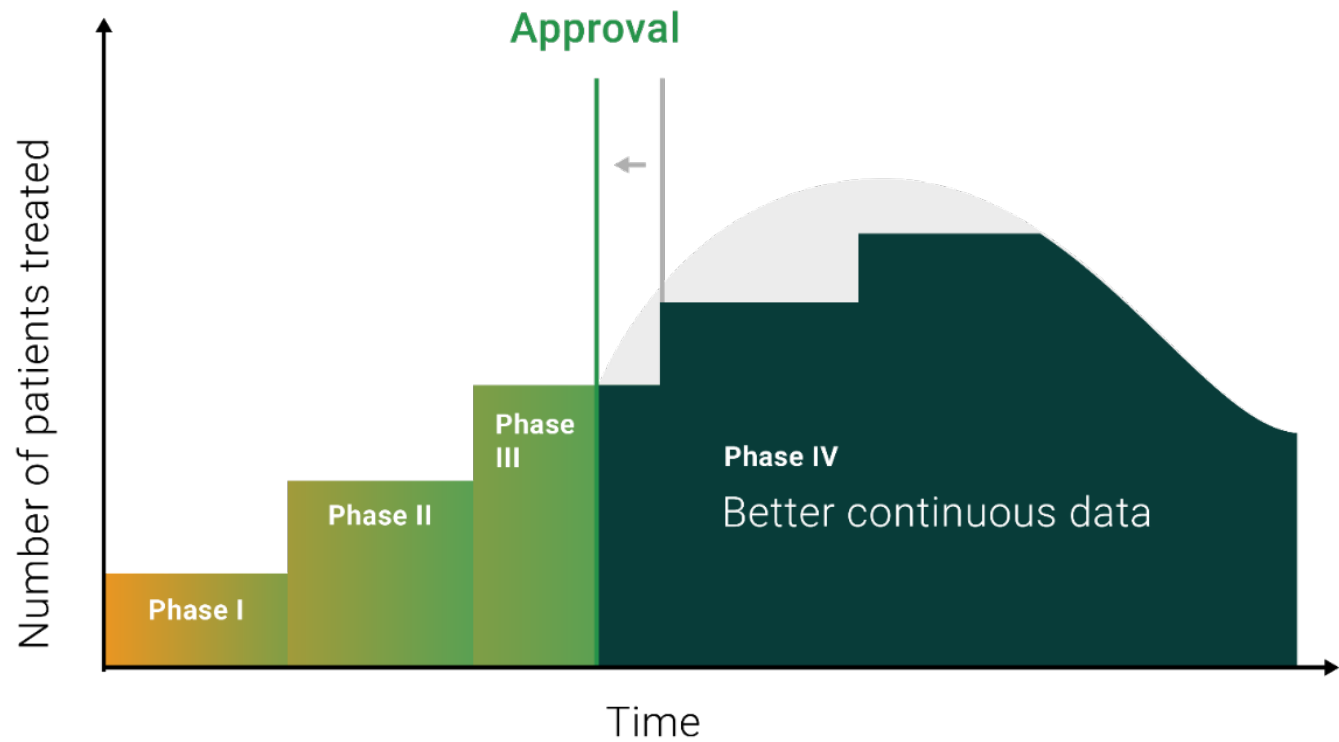


# Clinical evidence generation today



# Clinical evidence generation of the future

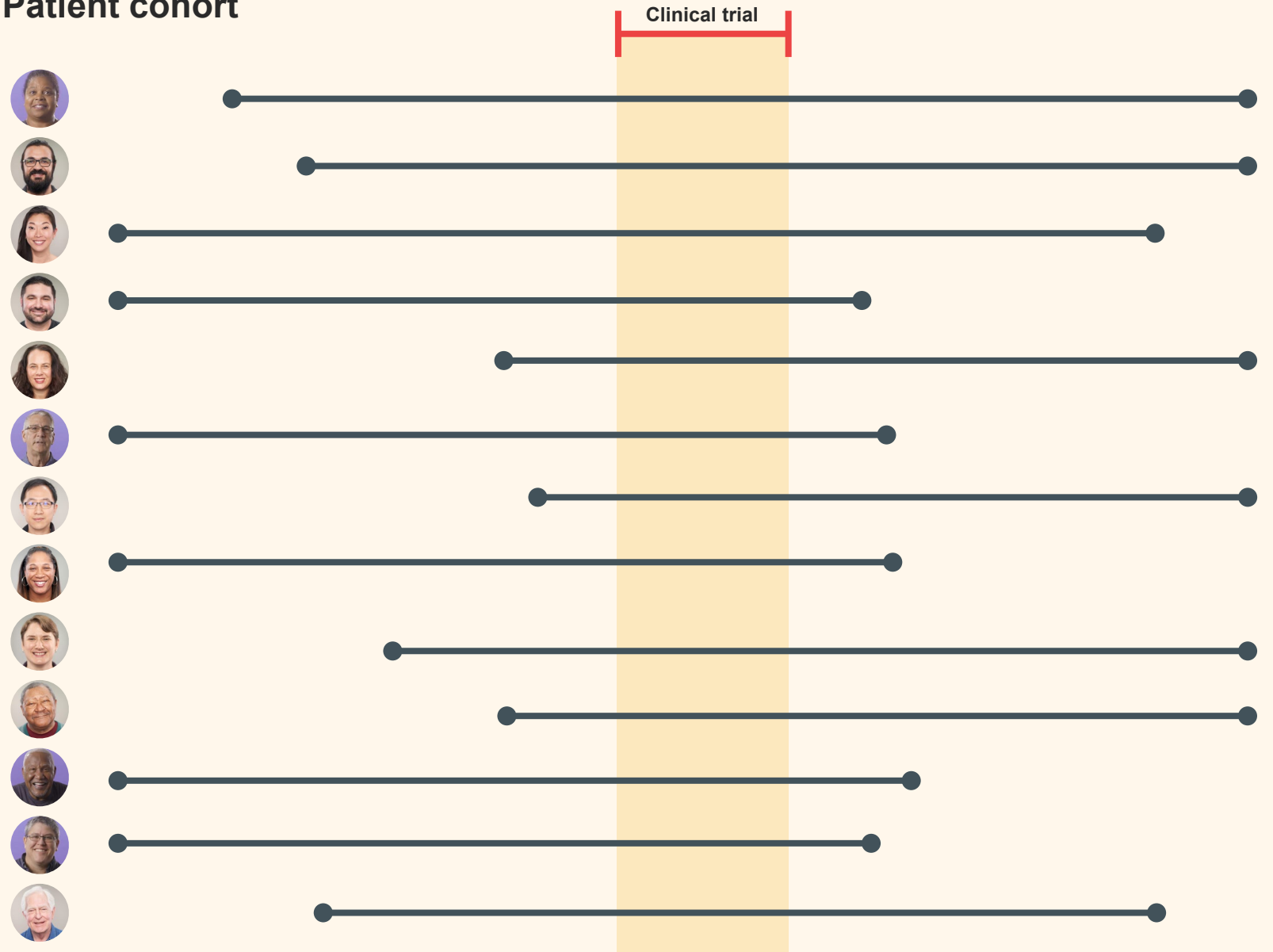
Earlier approval with better continuous data



# Longitudinal health data

Follows a patient's  
lifespan

Patient cohort



# Data will come from multiple sources



**Clinical trial**



**EHR**



**Claims**



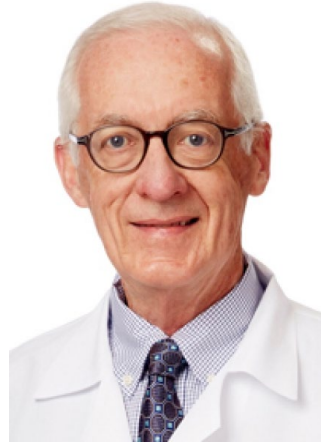
**Biology**



# Panel Discussion



Louise Guy  
*Argenta Advisors*



Michael Mack  
*Baylor Scott and White Health*



Joe Franklin  
*Verily*

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- What are other important challenges to patient access to these devices after a product receives coverage? What are some of the opportunities to improve patient access?

# Next Steps

*Josh Makower, Stanford Byers Center for Biodesign  
Mark McClellan, Duke-Margolis Center for Health Policy*

*1:50 – 2:00pm ET / 10:50 – 11:00am PT*

# Thank You

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