

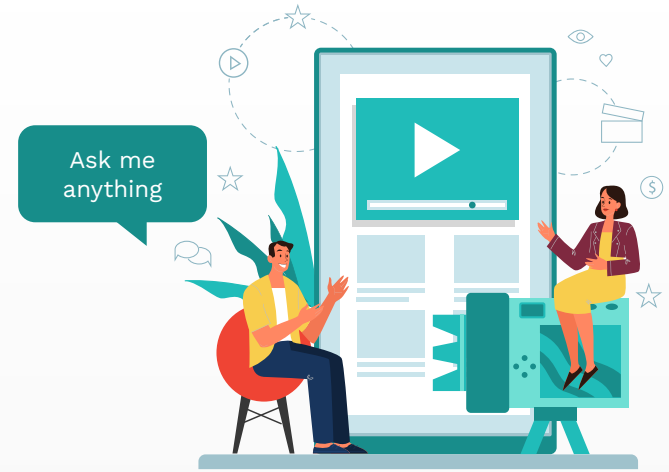


# Virtual Journal Club

Wednesday, October 16

11:00am ET

## Net financial benefits of digital endpoints publication in Clinical and Translational Science



**Joseph A. DiMasi**

Director of Economic Analysis and Research, Associate Professor, Tufts Center for the Study of Drug Development Tufts Medical School



**Jennifer C. Goldsack**

CEO Digital Medicine Society



**Ute Conradi**

Head of the innovation hub „Creative Lab“ Senior Lead, Operational Excellence, UCB BioSciences GmbH



**Thomas Metcalfe**

Personalised Healthcare Ecosystems, Roche Pharma Product Development Roche



**Lesley R. Maloney**

Global Regulatory Policy, Digital Health & Integrated Solutions Genentech



**Sarah Valentine**

Partnerships Lead, Life Sciences Digital Medicine Society



**Bert Hartog**

Chief Impact & Innovation Officer Digital Medicine Society

# But first, housekeeping

- Please note today's session is being recorded
- To ask a question for discussion during Q&A, please:
  - Either 'raise your hand' in the participant window and moderator will unmute you to ask your question live, or
  - Type your question into the chat box
- Slides and recording will be available after today's session

# Panelist Introductions

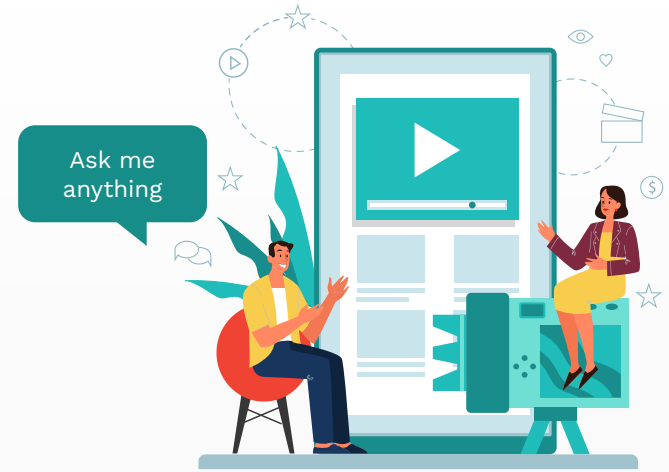


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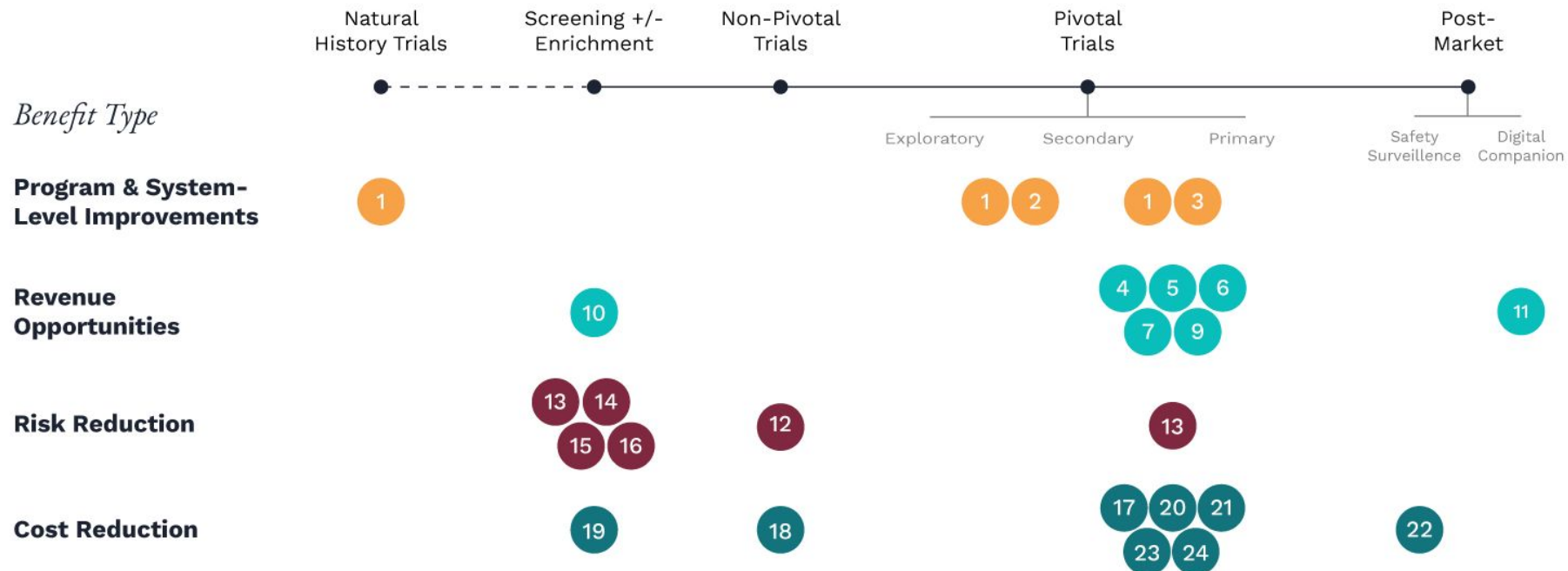
Partnerships Lead, Life Sciences  
Digital Medicine Society



**Bert Hartog**

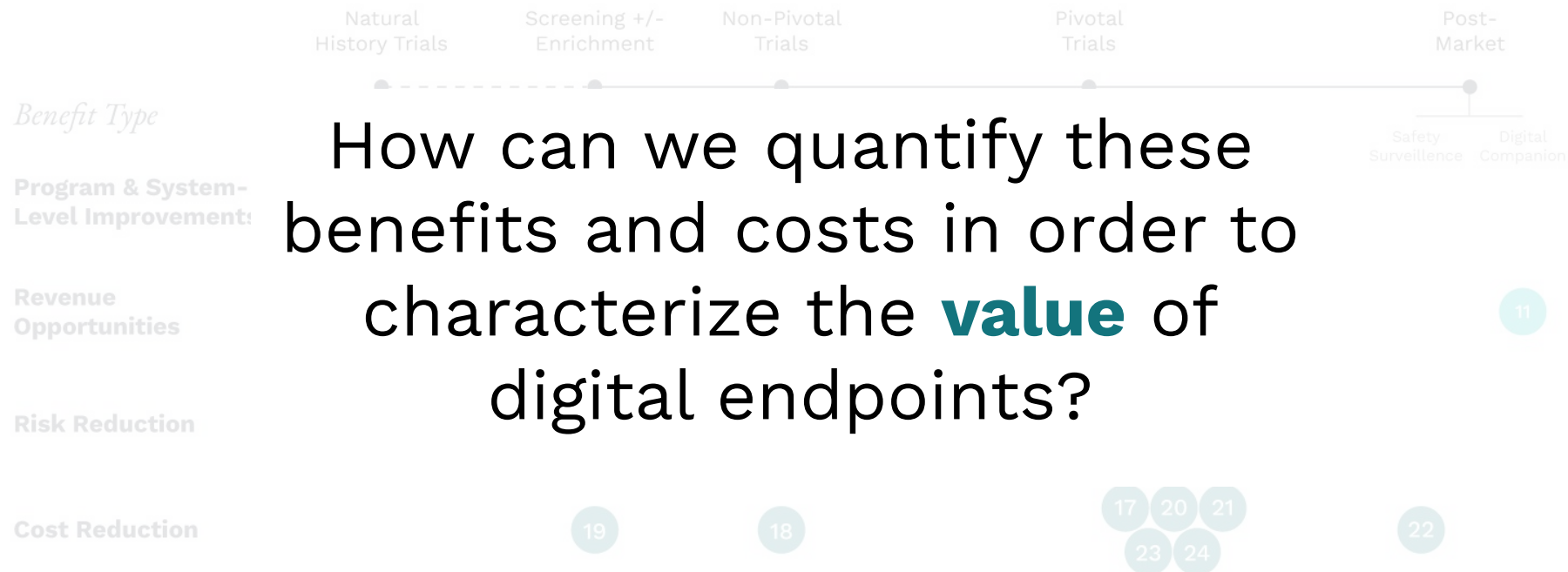
Chief Impact & Innovation Officer  
Digital Medicine Society

# The *landscape of benefits* accompanying the use of digital clinical measures in medical product development



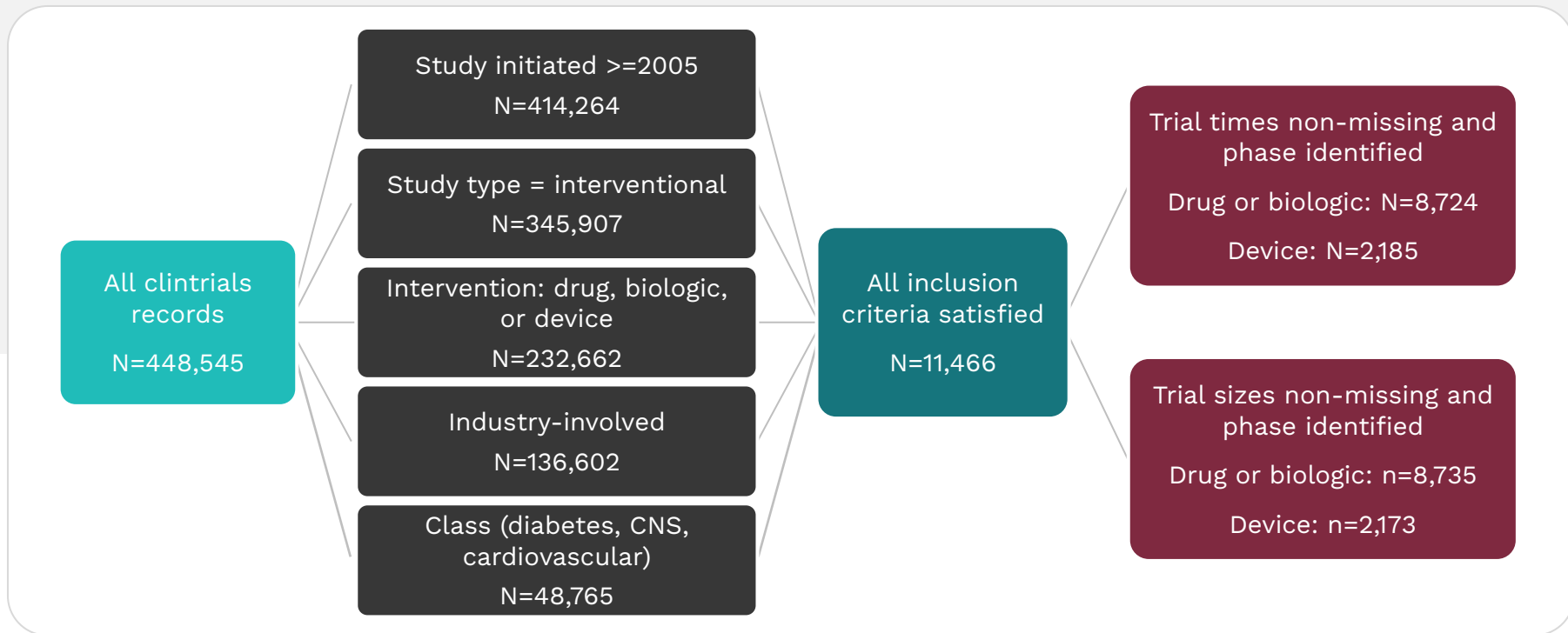
The descriptions of each benefit can be found in the following slides, organized by type of benefit

# The *landscape of benefits* accompanying the use of digital clinical measures in medical product development

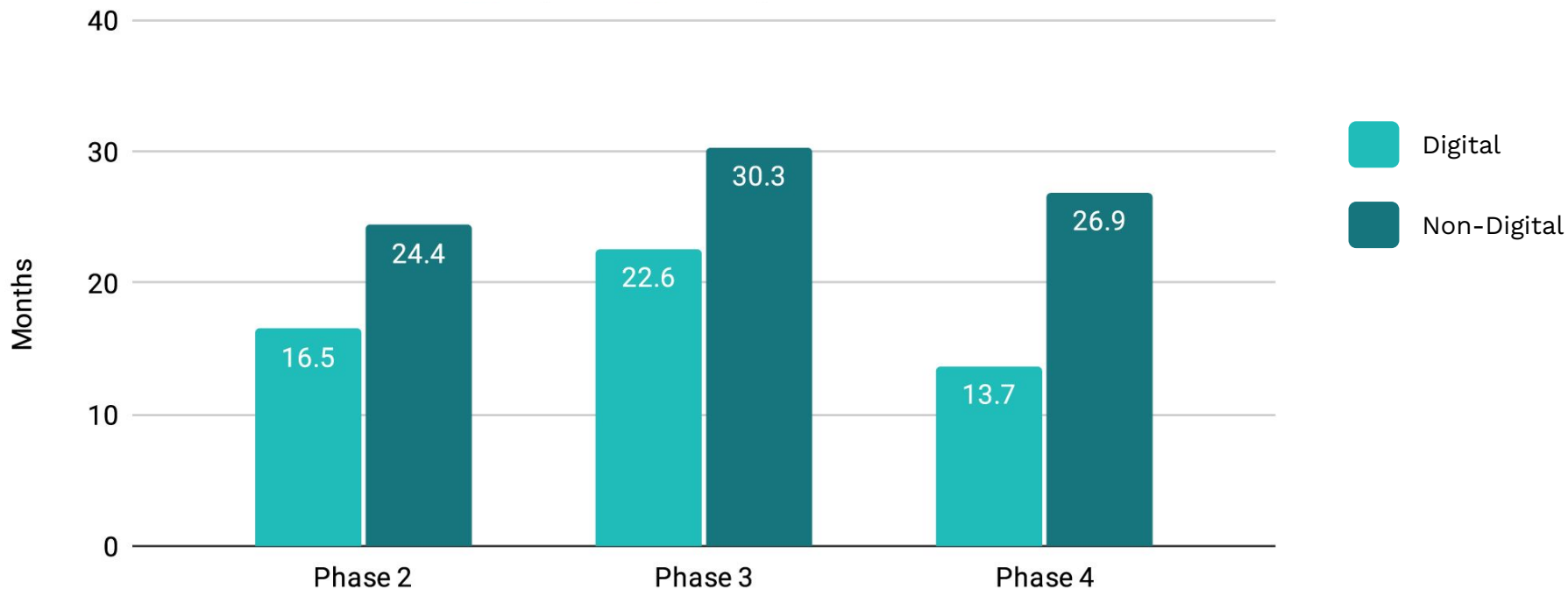


The descriptions of each benefit can be found in the following slides, organized by type of benefit

# Study Inclusion Criteria and Sample Size

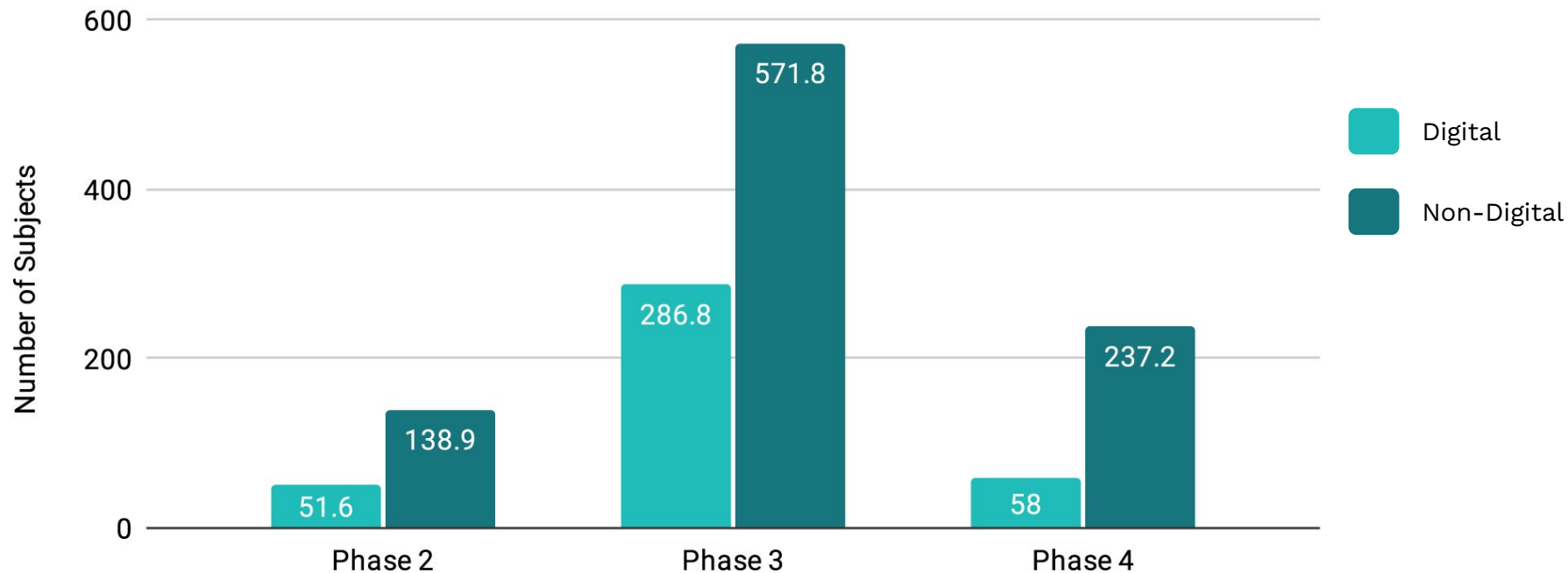


# Average Duration for CNS Trials by Phase (drugs and biologics)





# Average Enrollment for CNS Trials by Phase (drugs and biologics)



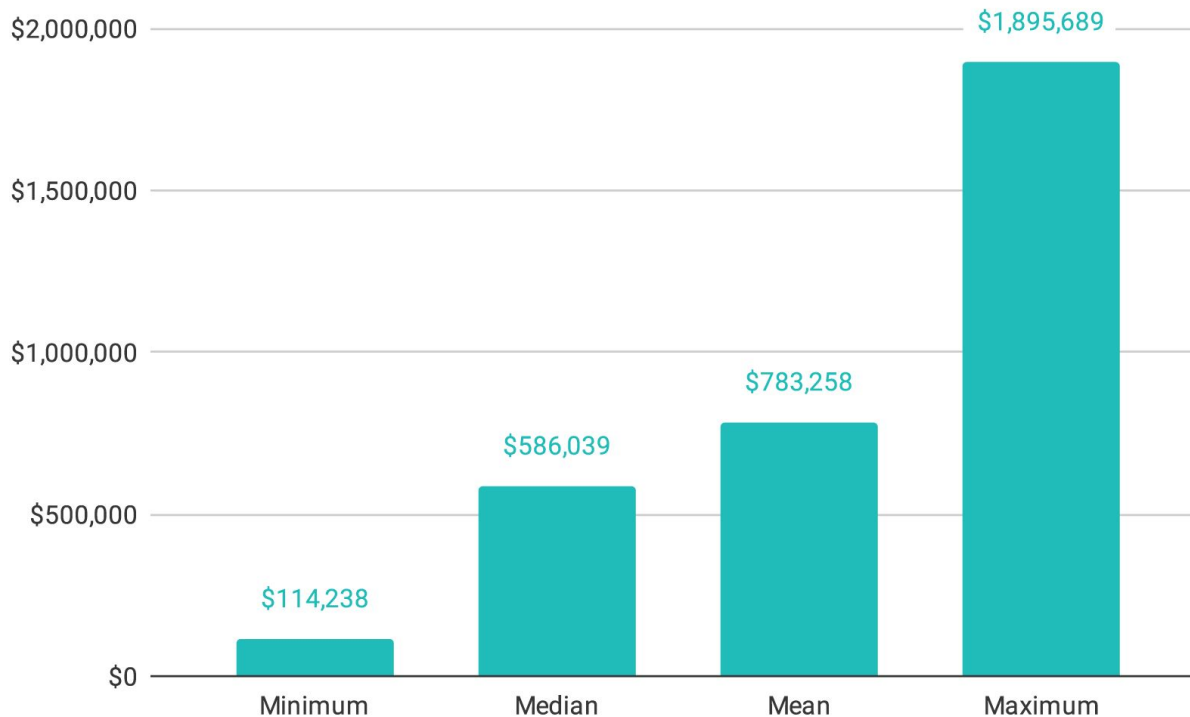
# Predicted Reductions in Trial Duration (mos.) and Enrollment with Digital Endpoints by Phase

	Phase 2 Duration			Phase 3 Duration			Phase 2 Enrollment			Phase 3 Enrollment		
	Predicted	Absolute decrease	Percent decrease	Predicted	Absolute decrease	Percent decrease	Predicted	Absolute decrease	Percent decrease	Predicted	Absolute decrease	Percent decrease
<b>Diabetes</b>												
Non-digital	13.7			18.2			130.8			312.6		
Digital	10.4	3.3	24.0%	14.2	4.0	22.0%	115.6	15.2	11.6%	276.0	35.6	11.7%
<b>CNS</b>												
Non-digital	17.4			23.9			109.3			277.0		
Digital	13.3	4.2	24.0%	18.7	5.2	22.0%	94.1	15.2	13.9%	244.6	32.4	11.7%
<b>Cardio</b>												
Non-digital	14.8			21.9			93.0			181.2		
Digital	11.2	3.5	24.0%	17.0	4.9	22.0%	77.7	15.2	16.4%	160.0	21.2	11.7%

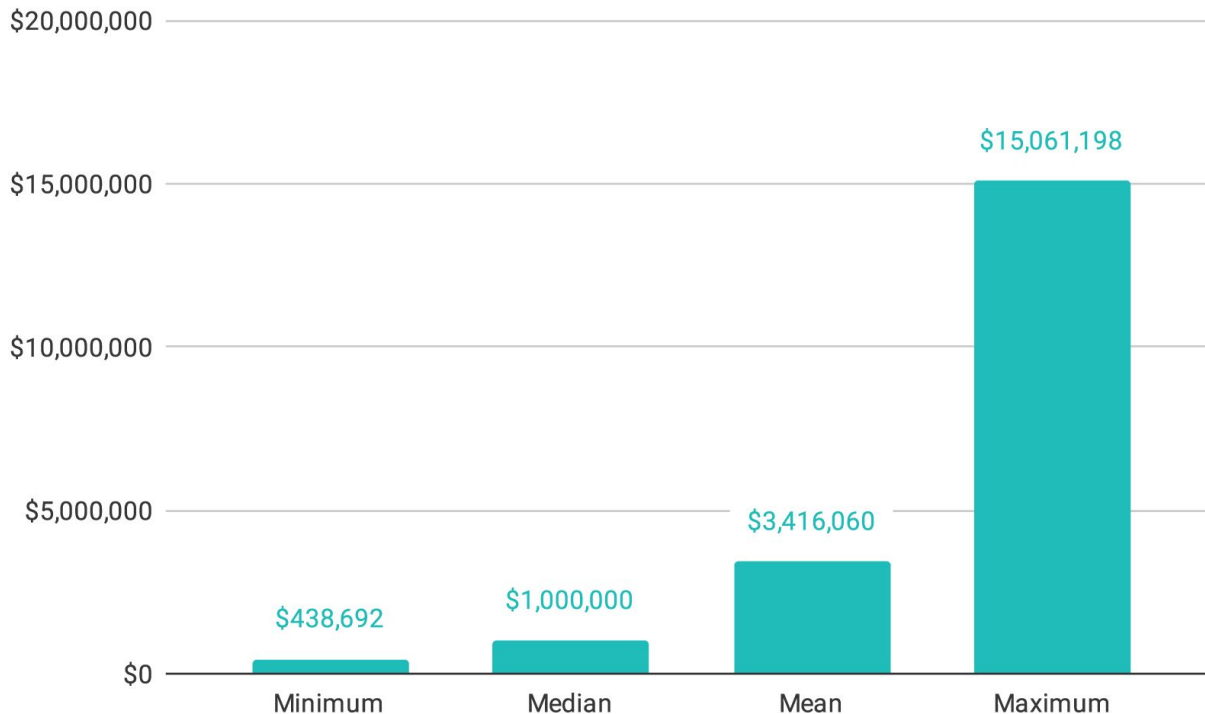
# Quantifying the Costs: Data and Methods

- We developed **two** related surveys on the development, validation, and utilization of digital endpoints in clinical trials
  - One for trial sponsors
  - One for developers of the digital measures or digital measurement technologies used to gather data for digital endpoint measures.
- Responses were gathered in July-August 2023
- A total of **71 responses** were received
  - 10 substantive responses from trial sponsors
  - 10 substantive responses from digital measures and/or technology developers

# Trial Sponsor Agreement Costs for Inclusion of Digital Endpoint Measures in Clinical Trials (2023 USD)



# Sponsor Costs from Implementing, Developing, and Validating Digital Endpoints in Clinical Trials (2023 USD)



# eNPV Modeling

## Widely used approach to evaluate investments

- Does not directly measure ‘strategic’ and intangible value

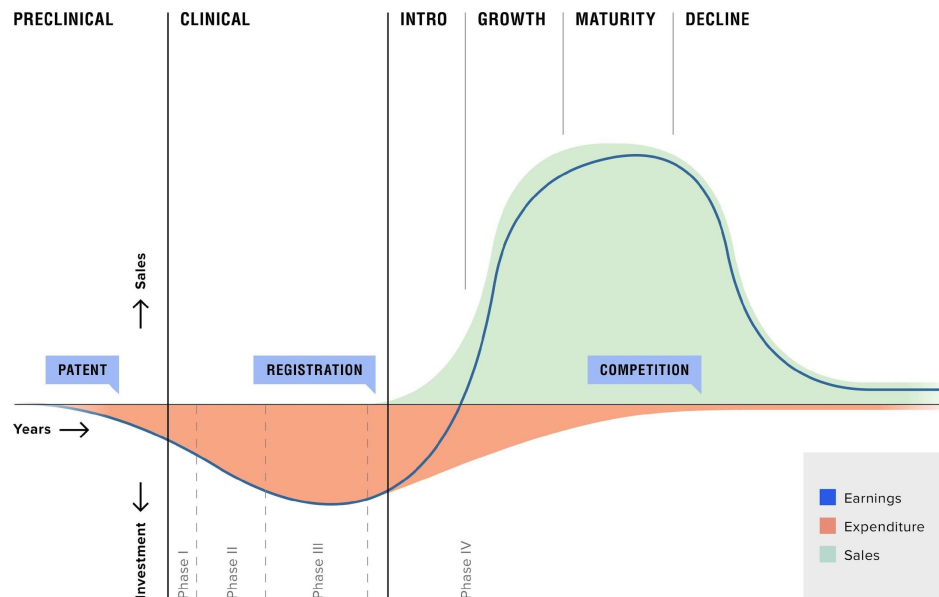
## Risk-adjusted measure

- Technical and regulatory risk

## Cash flows discounted (WACC)

- Outflows (e.g., direct drug development operating and commercialization expenses)
- Inflows (e.g., commercialization revenue)

**Value Drivers:** Time, Success, Cost, Revenue



# eNPV Modeling - Parameters and Data Sources

Parameter	Data Source	Parameter	Data Source
Development and review times	DiMasi et al., <i>J Health Econ</i> 2016;47:20-33 and CSDD protocol database	Peak sales and years to peak	Cortellis pipeline database (consensus analyst forecasts)
Development costs	DiMasi et al., <i>J Health Econ</i> 2016;47:20-33 and CSDD protocol database	Effective tax rate	Public financial data for top 10 pharma firms
Phase success rates	BIO/Informa/QLS, Feb 2021	Digital endpoint implementation cost	CSDD/DiMe Sponsor and Developer Cost Survey
Cost of capital	DiMasi et al., <i>J Health Econ</i> 2016;47:20-33	Change in trial duration	ClinicalTrials.gov and DiMe databases
Approved supplemental indications	Drugs@FDA	Change in trial size	ClinicalTrials.gov and DiMe databases

# Increase in eNPV and ROI per **Phase 2** Investigational Indication for Digital Endpoint Clinical Trials (2023 USD) by Therapeutic Area

Therapeutic Area	Reduction in Phase Duration (mos.)	Reduction in Trial Size	Mean sponsor implementation cost		Median sponsor implementation cost	
			eNPV delta	ROI	eNPV delta	ROI
<b>Diabetes</b>	3	16.4%	\$3.3M	0.477x	\$7.0M	3.5x
<b>CNS</b>	4	13.9%	\$2.1M	0.305x	\$5.8M	2.9x
<b>Cardiovascular</b>	4	11.0%	\$2.2M	0.324x	\$6.0M	3.0x



# Increase in eNPV and ROI per **Phase 3** Investigational Indication for Digital Endpoint Clinical Trials (2023 USD) by Therapeutic Area

Therapeutic Area	Reduction in Phase Duration (mos.)	Reduction in Trial Size	Mean sponsor implementation cost		Median sponsor implementation cost	
			eNPV delta	ROI	eNPV delta	ROI
<b>Diabetes</b>	4	11.7%	\$40.2M	5.9x	\$43.9M	21.9x
<b>CNS</b>	5	11.7%	\$24.2M	3.5x	\$27.8M	13.9x
<b>Cardiovascular</b>	5	11.7%	\$27.4M	4.0x	\$30.9M	15.5x

# What do these findings mean?

**This is the first of its kind study**

This is just the tip of the iceberg



**We've long surmised that digital endpoints can reduce trial size and duration**

Now we have data to back it up



**Yes, there's an investment up front needed in order to develop and deploy digital measures**

And there's a significant return on that investment, not to mention the opportunity for further returns through scale



**Organizations can achieve significant ROI by implementing digital endpoints**

If going at it alone yields such significant value, think about the value we can achieve by sharing costs and risks



# Stay tuned for resources in Q1 2025!



## Building the **Business Case** for Digital Endpoints

*Establishing the business case for adoption of digital endpoints in clinical trials*

### Project Partners



The Project Partners section features a grid of logos for various organizations. The logos are arranged in five rows and six columns. The partners include:

- Row 1: abbvie, ActiGraph, ANALOG DEVICES, Biofourmis, BLUESKEYE AI, Brain & Mind, CHEO RESEARCH INSTITUTE, CHUGAI, Roche Roche Group
- Row 2: COPD FOUNDATION, COSIRUSS, CRITICAL PATH INSTITUTE, Cumulus, EVMS Eastern Virginia Medical School, evinova, Exponent, FDA
- Row 3: Genentech A Member of the Roche Group, Health Advances, IMPERIAL, koneksa, MERCK, Mitsubishi Tanabe Pharma America, Mobilise-D, modality.ai
- Row 4: OmniScience, REGENERON, Roche, Sama, sanofi, seuss, strados, sysnav
- Row 5: TECH DOCTOR, TNO innovation for life, Tufts Center for the Study of Drug Development TUFTS UNIVERSITY, AT THE FOREFRONT UChicago Medicine, VERISIMLife, viro SENSE, WKD.SMRT



# Scaling Digital Health



Join us for our upcoming **Scaling Digital Health** project to support the continued development, adoption, and scale of digital health capabilities within pharmaceutical and biotech organizations



## PEDIATRIC RARE DISEASE



*Digital Measures Development*



Join us defining a core digital measures set for **pediatric rare disease** to accelerate research and transform care



New resources launch on Thursday, November 14!

ALZHEIMER'S DISEASE  
& RELATED DEMENTIAS

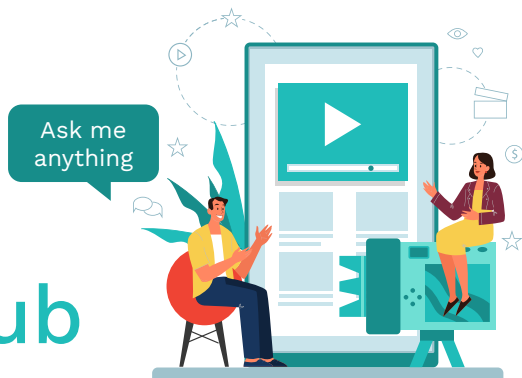


*Digital Measures Development*



Scan the QR code to register for this **free webinar on 11/14 at 11 a.m. ET!**

# Virtual journal club



## Regulatory Pathways for Qualification and Acceptance of Digital Health Technology-Derived Clinical Trial Endpoints: Considerations for Sponsors



Wednesday, October 30, 2024

11:00am ET



**Elena Izmailova**

CSO  
Koneksa Health



**Jessie Bakker**

*Vice President of Clinical  
Development*  
Koneksa Health



**Benjamin Vandendriessche**

*VP, Science*  
Digital Medicine Society (DiMe)  
Moderator



# Thank you



<https://dimesociety.org/>



[linkedin.com/company/dime-society](https://www.linkedin.com/company/dime-society)