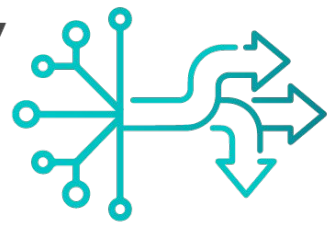




Digital Health
**Regulatory
Pathways**



A Path Forward: New Tools to Navigate Digital Health Regulations

Public launch event

March 1, 2023 | 1:00pm - 2:30pm ET



Brendan O'Leary

Deputy Director, Digital
Health Center of
Excellence, FDA
Keynote



Jennifer Goldsack

Chief Executive Officer,
Digital Medicine
Society, DiMe
Moderator

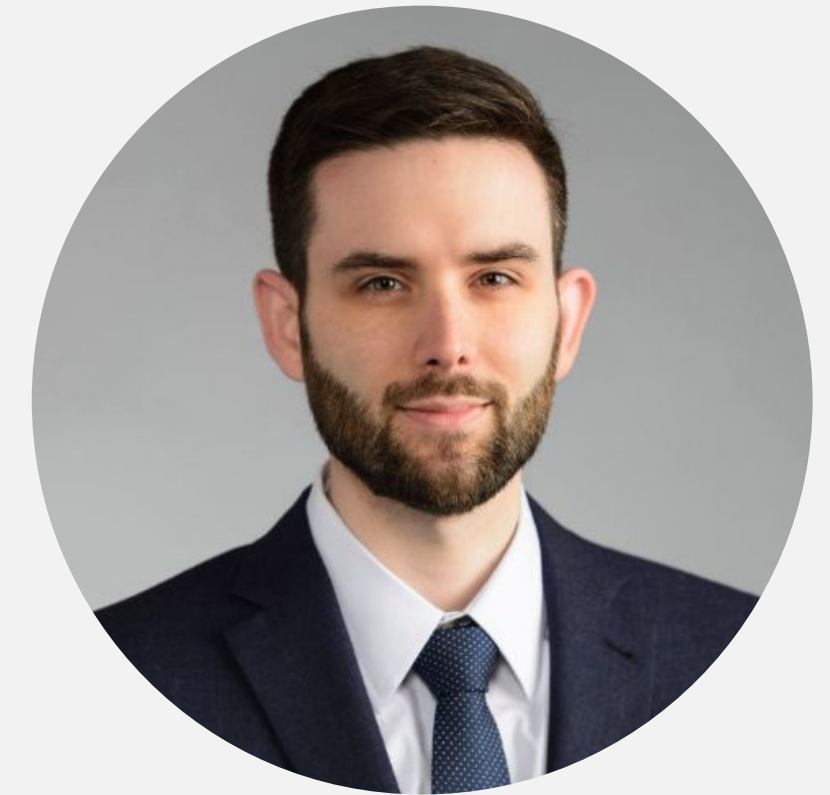


Digital Health
**Regulatory
Pathways** 

The icon consists of a teal circuit-like line with circular nodes at the end of each branch, leading to three curved arrows pointing to the right.

A Path Forward: New Tools to Navigate Digital Health Regulations

Wednesday, March 1, 2023 | 1:00pm ET



With keynote remarks by
Brendan O'Leary
Deputy Director, Digital
Health Center of
Excellence, **FDA**

A Path Forward: New Tools to Navigate Digital Health Regulations



Brendan O'Leary
Deputy Director,
Digital Health
Center of
Excellence
FDA



Marisa Cruz
Chief Medical Officer
Empatica



Megan Doyle
Director, Global Regulatory
and R&D Policy
Amgen



Nikki Batista
Senior Director,
Digital Health
Regulatory Affairs
MCRA



Ryan Hoshi, Ph.D.
Director, Regulatory
Policy and Intelligence
AbbVie



Sari Kaganoff
General Manager,
Consultant
Rock Health



Steve Berman
Director,
Translational
Regulatory Affairs
AstraZeneca



Jen Goldsack
(Moderator)
CEO
DiMe



Smit Patel (Moderator)
Associate Director
DiMe

Digital Health
Regulatory
Pathways 





A Path Forward: New Tools to Navigate Digital Health Regulations

Public Launch Event

March 1, 2023 | 1:00pm ET

Project Partners



Digital Health Regulatory Pathways



A Path Forward: New Tools to Navigate Digital Health Regulations

Public Launch Event

March 1, 2023 | 1:00 pm ET

A recent survey of the digital medicine community revealed that:



25% of digital health solution developers don't know if the product they're developing is regulated.



Of those respondents who knew their product was regulated,

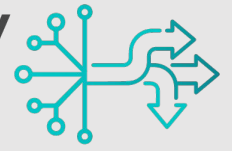
3 out of 4

don't know the optimal regulatory pathway.

Public Launch Event

March 1, 2023 | 1:00pm ET

Digital Health
Regulatory
Pathways



New DiMe project resources will help you answer...



Should my digital health solutions be regulated?



Where can I find more information on digital health regulations?



What regulatory pathway applies to my digital health solution?



How will a regulatory strategy inform my commercial success?

A Path Forward: New Tools to Navigate Digital Health Regulations

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Digital Health Regulatory Pathways



A Path Forward: New Tools to Navigate Digital Health Regulations

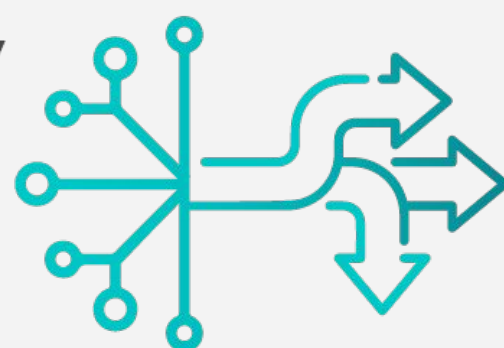
March 1, 2023 | 1:00pm ET

50+ open-access resources designed to help you navigate digital health regulations, optimize regulatory strategy for your business, and interact with regulators early, often, and transparent to develop digital health products





Digital Health Regulatory Pathways



Navigating digital health regulations to optimize product development, strategy, and decision-making.

Project Partners





THANK YOU



@_DiMeSociety



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

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3 out of 4

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Driving Inclusion in Digital Health Measurement Product Development & Deployment

May 25, 2022, 11:00am - 1:00pm (ET)

The first set of open-access resources designed to ensure that digital health measurement products are developed and deployed with and for all individuals who can benefit from them



Amy Sheon
NDIA



Anindita (Annie) Saha
FDA



Ariel Dora Stern
Harvard Business School and Hasso
Plattner Institute Digital Health
Center



Bray Patrick-Lake
Evidation Health



Carrie Northcott
Pfizer



Celine Marquez
Genentech



Ernest Moy
VHA



Jamileh Jemison
MindMed



Jeanne Chung
DiMe



Jennifer Goldsack
DiMe



Kalvin Yu,
Becton, Dickinson & Co.



Kristin Size
Verily



René Quashie
CTA



Silas Buchanan
Institute for eHealth Equity



Yashoda Sharma
DiMe