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
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
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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.
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?

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Digital Health Regulatory Pathways
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
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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

Bray Patrick-Lake
Evidation Health

Ernest Moy
VHA

Jennifer Goldsack
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René Quashie
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