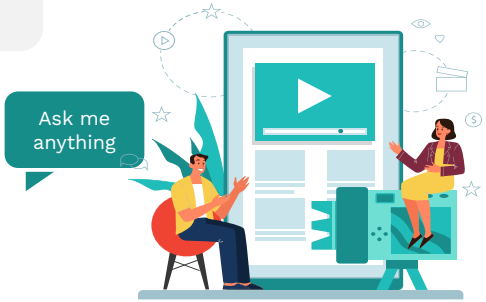
Virtual Journal club



Springer Link

Regulatory Acceptance of Patient-Reported Outcome (PRO) Data from Bring-Your-Own-Device (BYOD) Solutions to Support Medical Product Labeling Claims

June 16, 2022 11 am ET

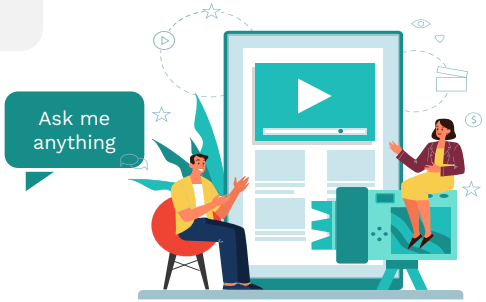
Florence D. Mowlem PhD
Director, eCOA
Medable

Jennifer Goldsack, MBA
CEO
DiMe
Moderator

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

Virtual Journal club



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Key Points

- Hesitation from trial sponsors due to:
  - concerns around **data quality, integrity, and variability**
  - **regulatory acceptance** uncertainties
  - **lack of formal guidance** around BYOD from regulators

- So, important considerations for BYOD concern the conservation of the measurement properties of validated instruments when used on screens of different sizes, and the technical and practical considerations related to use of the patient's own mobile devices or computers

Key Points

A regulatory approved labelling claim based on ePRO data collected using BYOD has occurred!!!!!

The Pfizer and BioNTech mRNA Vaccine study for the treatment of COVID-19 collected PRO safety data from over 40,000 participants worldwide using an electronic diary, with 79% of participants using their own device (BYOD) and 29% using a provisioned device.

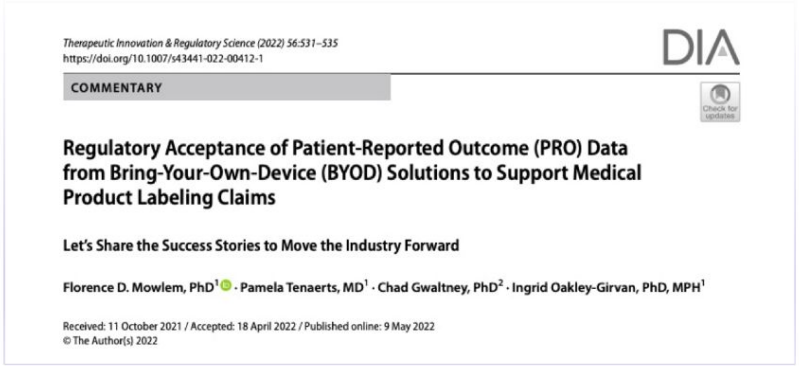
BUT……. We need more evidence……

Sponsor	TI	Product name	Study phase	Endpoint position and Type	PROM	PRO endpoint	% of BYOD	ClinicalTrials.gov identifier	Approval agencies	PI link
BioNTech SE, Pfizer	COVID-19	COMIRNATY	Phase 3	Primary safety	Solicited local and systemic reaction diary	% of participants reporting the following for 7 days after Dose1, 2, and 3: pain, redness, and swelling at injection site, fatigue, headache, muscle pain, chills, joint pain, fever, vomiting, diarrhea	79%	NCT04713553	FDA, EMA	https://www.fda.gov/media/151707/download

TI therapeutic indication, *PROM* patient reported outcome measure, *BYOD* bring your own device, *PI* package insert

A call to action:

Pledge your intention to contribute to a database of PRO endpoints captured via BYOD used in medical product labelling



Therapeutic Innovation & Regulatory Science (2022) 56:531–535
https://doi.org/10.1007/s43441-022-00412-1

DIA

COMMENTARY

Regulatory Acceptance of Patient-Reported Outcome (PRO) Data from Bring-Your-Own-Device (BYOD) Solutions to Support Medical Product Labeling Claims

Let's Share the Success Stories to Move the Industry Forward

Florence D. Mowlem, PhD[1] · Pamela Tenaerts, MD[1] · Chad Gwaltney, PhD[2] · Ingrid Oakley-Girvan, PhD, MPH[1]

Received: 11 October 2021 / Accepted: 18 April 2022 / Published online: 9 May 2022

https://lnkd.in/e-VZe7e2

Article link: https://link.springer.com/article/10.1007/s43441-022-00412-1

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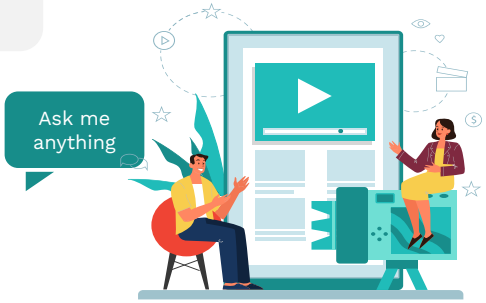

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IMPACT

Virtual First Medical Practice Collaboration

Care Transitions Supporting Effective Virtual First Care (V1C)

Public Launch Event

June 28, 2022 | 1:30 p.m. ET

ata DMS DIGITAL MEDICINE SOCIETY

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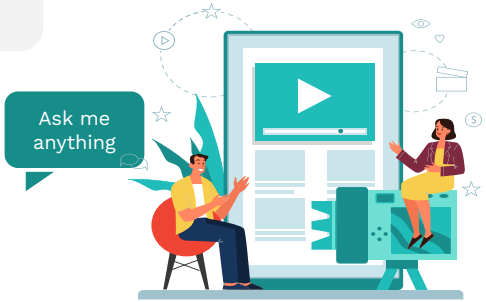

DATAcc

Digital Health Measurement Collaborative Community

Moving from “Should Do” to “How To”
A deep dive into the DATAcc Toolkits for Inclusivity with the creators

July 12, 2022 11am ET

Jamileh Jemison, MD, MS
Clinical Research Coordinator
MindMed

Jeanne Chung
Program Lead
DiMe

Justin Ranton
Director, Head of UX
AliveCor

Nicole Braccio, PharmD, RPh
Policy Analyst & Pharmacist
National Patient Advocate Foundation

Mitchell Tang
Doctoral Student
Harvard Business School

Yashoda Sharma
Program Director
DiMe
Moderator

DIGITAL MEDICINE SOCIETY

Sensor data integrations to power better decisions, faster, across healthcare & research

Public launch event

July 18, 2021 | 10.30am - noon ET

Micky Tripathi
National Coordinator for Health Information Technology, HHS
Keynote

Jennifer Goldsack
Chief Executive Officer, Digital Medicine Society, DiMe
Moderator

THANK YOU

DIGITAL MEDICINE SOCIETY

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