

Passive Sensing and Active Data Collection in Clinical Trials: Filing the Gaps Between Efficacy and Effectiveness

February 23, 2022 | Washington, DC | ISCTM

Shaheen E. Lakhan, MD, PhD, FAAN
Chief Medical Officer,
Click Therapeutics

John P. Docherty, MD
Adjunct Professor of Psychiatry,
Weill Cornell Medicine

Disclosures

SEL

- Employment – Click Therapeutics
- Consulting – Shaheen Lakhan, MD; Cambridge Health Alliance; Mount Auburn Hospital; Lin Health; Thriveworks; Remedy Health; Dotdash

JPD

- Consulting – Medable; Owl Consulting, LLC; Click Therapeutics; Kinstsugi; Otsuka Pharmaceutical

Legacy



System

- Location Bound
- Temporally Limited



Assessments

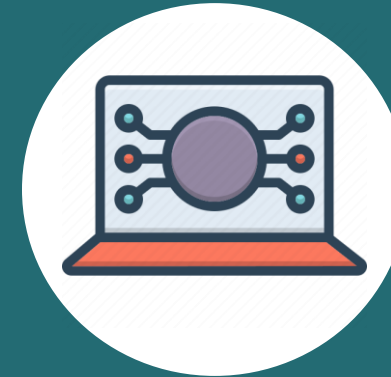
- Occasional
- Subjective
- Active



Data

- Delayed
- Redundant Entry
- Siloed Database

Digital



System

- Location Free
- Temporally Extended



Assessments

- Continuous
- Objective
- Passive



Data

- Immediate
- Direct Entry
- Integrated Database

Agenda

- Leveraging passive sensing in pharma clinical trials (Sean Kenny, MBA, *Biogen*)
- Passive sensing and smartphone-based tracking in clinical trials for migraine (Mia Minen, MD, MPH, *NYU Langone Medical Center*)
- Methodological considerations for passive sensing and smartphone-based tracking (Jessica Lipschitz, PhD, *Brigham and Women's Hospital*)
- Leveraging Ecological Momentary Assessment to improve treatment outcomes in clinical trials (Cassandra Snipes, PhD, *Click Therapeutics*)
- Panel & regulatory discussion (Moderators: JPD, SEL; Speakers: Elizabeth Kunkoski, MS, *FDA*; Lorenzo Guizzaro, MD, PhD, *EMA*; and session speakers)