



Virtual
Journal club





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How V3 might be applied to wearable dosimeters and light loggers



Jessie Bakker, MS PhD
Program Director
DiMe
Moderator

June 13th, 2023 11 a.m. ET



But first, housekeeping

- Please note today's session is being recorded
- Slides and recording will be available after today's session
- Please enter questions into the chat box throughout the session



V3 introduction

Design Specifications & Modular Prototyping VERIFICATION **ANALYTICAL** VALIDATION CLINICAL VALIDATION Clinical Utility

Evaluates and demonstrates the performance of a sensor technology within a **BioMeT**, and the sample-level data it generates, against a pre-specified set of criteria.

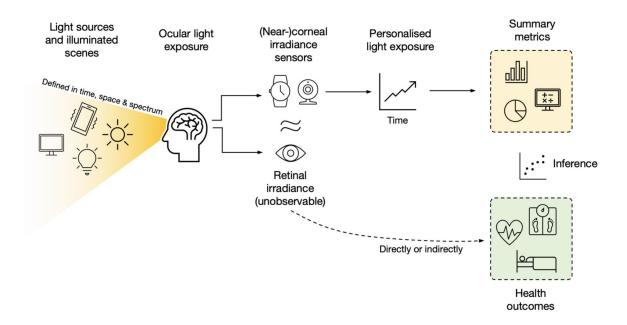
Evaluates the performance of the algorithm, and the ability of this component of the **BioMeT** to measure, detect, or predict physiological or behavioral metrics.

Evaluates whether a **BioMeT** acceptably identifies, measures, or predicts a *meaningful* clinical, biological, physical, functional state, or experience, in the stated context of use (which includes a specified population).

BioMeT - Biometric Monitoring Technology



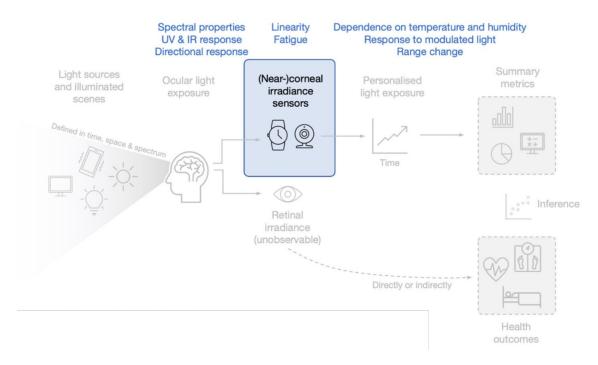
Light logger and dosimetry pipeline





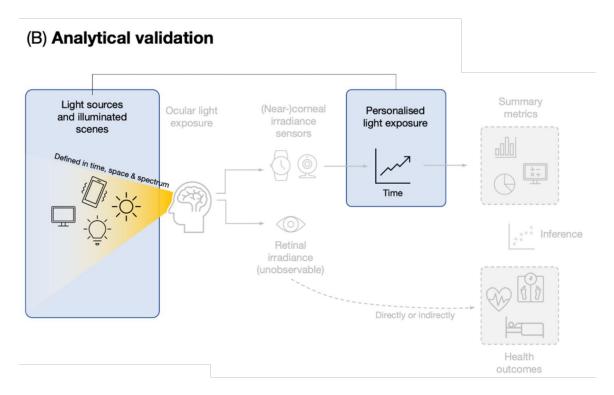
Verification

(A) Verification





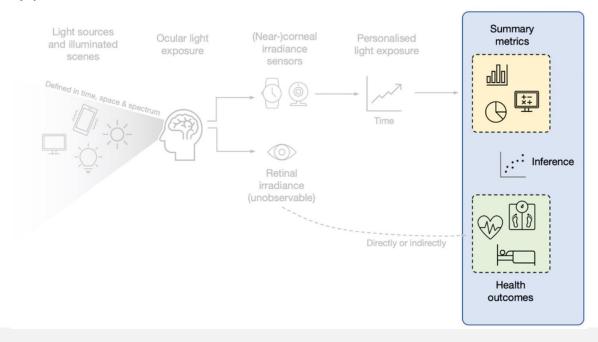
Analytical validation





Clinical validation

(C) Clinical validation





Current and future challenges

- To what extent is corneal light exposure a physiologically relevant quantity?
- What is the usability and acceptability of digital dosimeters?
- Which metrics should be used?
- How comparable are data from different groups and populations?
- How to handle non-wear periods and quality control?





Dr. Alan HamiltonSenior Director of Research **COPD Foundation**Panel Moderator



Candice Taguibao
Program Lead, PA Project
DiMe
Moderator



Bray Patrick-Lake
Senior Digital Health Specialist
FDA CDRH Digital Health Center of
Excellence



Salma AjraouiDigital Practice Lead, Patient
Centred Solutions
IQVIA



Eric Mangin
Global Digital Analytics and
Technologies
MSD



Elena Ismailova CSO Koneksa



Kieran F. Reid, PhD, MPH
Director, Laboratory of Exercise
Physiology and Physical
Performance
Brigham and Women's Hospital,
Harvard Medical School

Striding Past the 6MWT:

Complementing Physical Activity Assessment with a Consensus Set of Digital Clinical Measures

Tuesday, June 27 at 11am-12pm ET





Virtual
Journal club





Jenna Carl
Chief Medical Officer
Big Health



Paul Wicks Consultant Wicks Digital Health



Tim CampelloneVice President, Translational Science **Woebot Health**



Jordan Silberman
Director of Clinical Analytics &
Research
Elevance Health



Smit Patel
Associate Program Director
Digital Medicine Society (DiMe)
Moderator

Evidence DEFINED Framework – A Rigorous, Rapid Approach to Assess the Clinical Value of Digital Health Interventions | Public Launch Event

Thursday, July 20th, 2023 | 12pm ET



THANK YOU



