



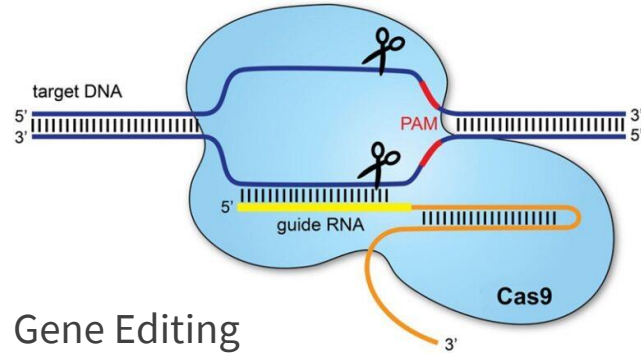
Changing perspectives in digital measure development

From what we could measure, to what we should measure

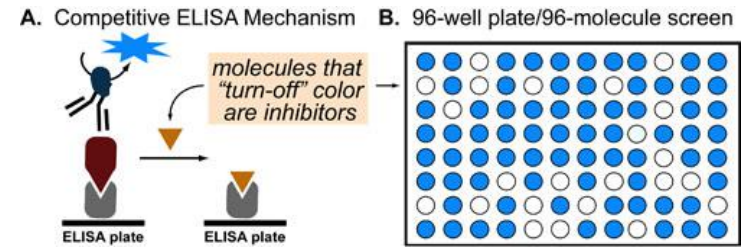
Ieuan Clay
VivoSense
March 2024

New technology, new insights?

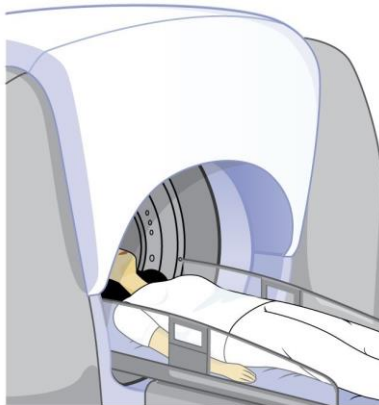
Development and adoption of new technologies have transformed various scientific fields



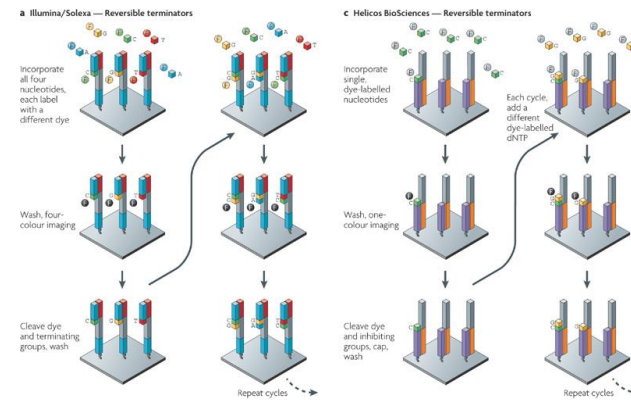
Gene Editing



HTS



MRI



Genomics

The single story creates stereotypes, and the problem with stereotypes is not that they are untrue, but that they are incomplete.

They make one story become the only story.

Chimamanda Ngozi Adichie

<https://youtu.be/D9lhs241zeg> & [Chimamanda Ngozi Adichie Comes to Terms with Global Fame | The New Yorker](#)

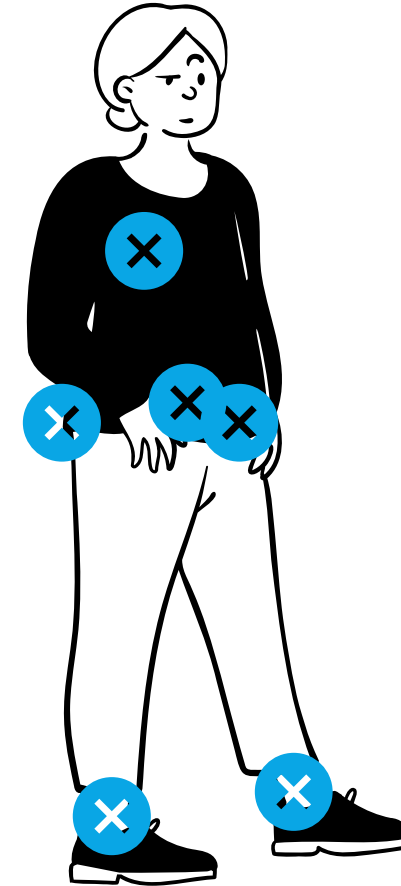


What could we measure?

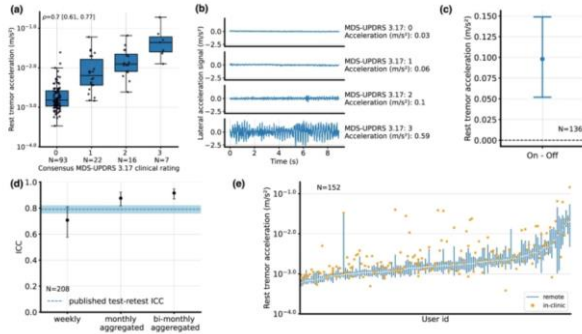
A typical example

written consent given by all participants. Each participant was asked to wear six IMU sensors:

- **One actibelt** (Trium Analysis Online GmbH, Germany) centered on the waist (*act*) (tri-axial accelerometer of range ± 6 g and sample rate of 100 Hz)
- **One BioStampRC** (MC10, Inc., USA) on the chest (*bst*) (tri-axial accelerometer of range ± 4 g, tri-axial gyroscope of ± 2000 deg/s and sample rate of 125 Hz)
- **Four Shimmer3** (Shimmer, Ireland), each on the waist (*shA*), lower back (*shP*), left (*shL*) and right ankle (*shR*) (tri-axial low-noise accelerometer of range ± 2 g, wide-range accelerometer of range ± 8 g and tri-axial gyroscope of ± 2000 deg/s; sample rate of 102.4 Hz)



Verily case study



[Virtual exam for Parkinson's disease enables frequent and reliable remote measurements of motor function | npj Digital Medicine \(nature.com\)](#)

- V3



Clinical Outcome Assessments (COA) Qualification Program DDT COA #000142: Virtual Motor Exam for Parkinson's Disease, Part III Estimator (VME Part III) Letter of Intent

Section 1. Administrative Structure
Description of the submitter including, but not limited to, principal investigator(s), working group member(s), institutions, and contact information.

[Clinical Outcome Assessments \(COA\) Qualification Program DDT COA #000142: Virtual Motor Exam for Parkinson's Disease, Part III Estimator \(VME Part III\) Letter of Intent \(fda.gov\)](#)

- Early engagement with regulators



DRUG DEVELOPMENT TOOL
LETTER OF INTENT DETERMINATION
DDT COA #000142

[FDA response](#)

- LOI Accepted



Dinesh Puppala, MS
Verily Life Sciences

What should we measure?

A convergence of pressures is changing how digital measures are developed



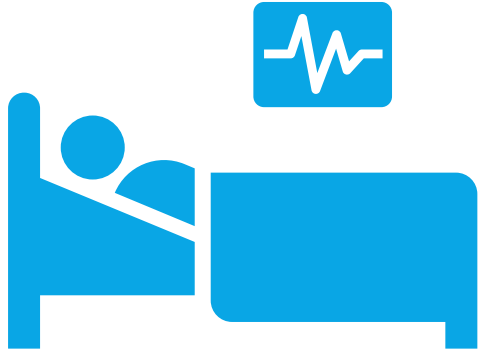
Sponsors



Payers & HCPS



Regulators

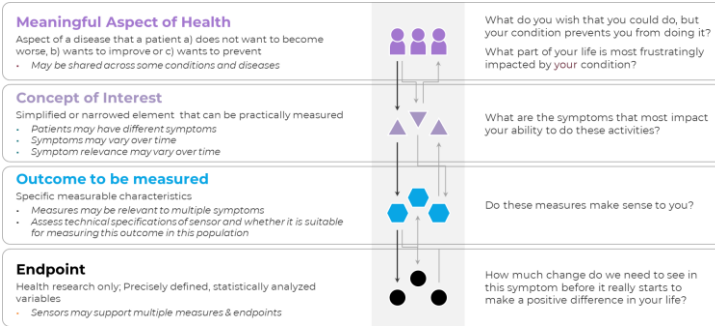


Patients & caregivers

Foundational work in developing new evidence tools

Pressure from patients, advocates and regulators is starting to pay off

Practical, aligned frameworks



[Digital Measures That Matter to Patients: A Framework to Guide the Selection and Development of Digital Measures of Health | Digital Biomarkers | Karger Publishers](#)

PFDD

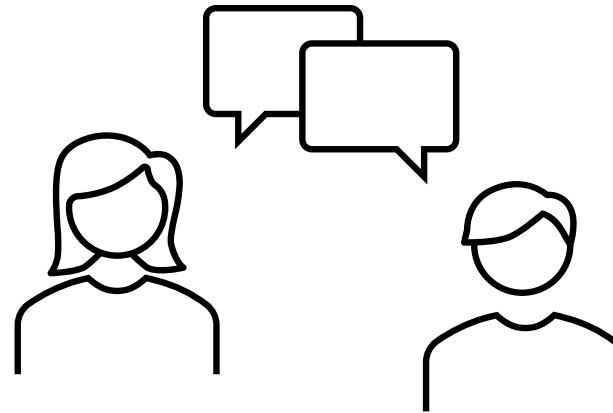
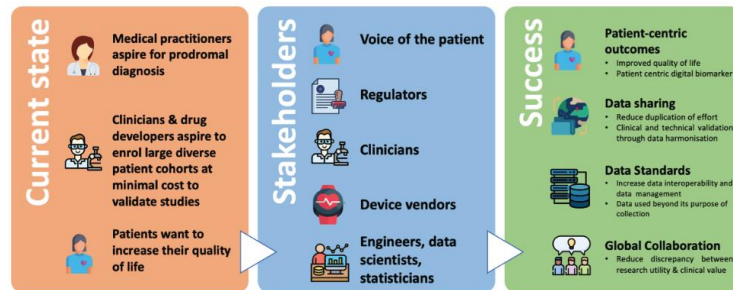


morethanskindeep-eczema.org



cancersupportcommunity.org

Advocacy and multistakeholder engagement



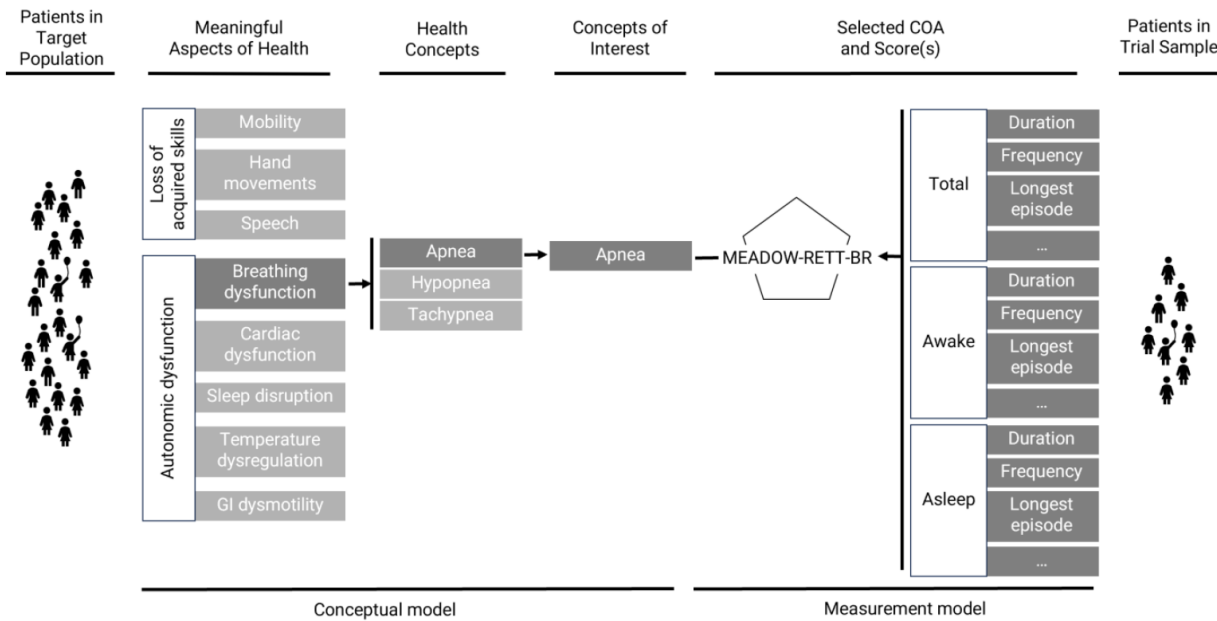
[Digital Progression Biomarkers as Novel Endpoints in Clinical Trials: A Multistakeholder Perspective - IOS Press](#)



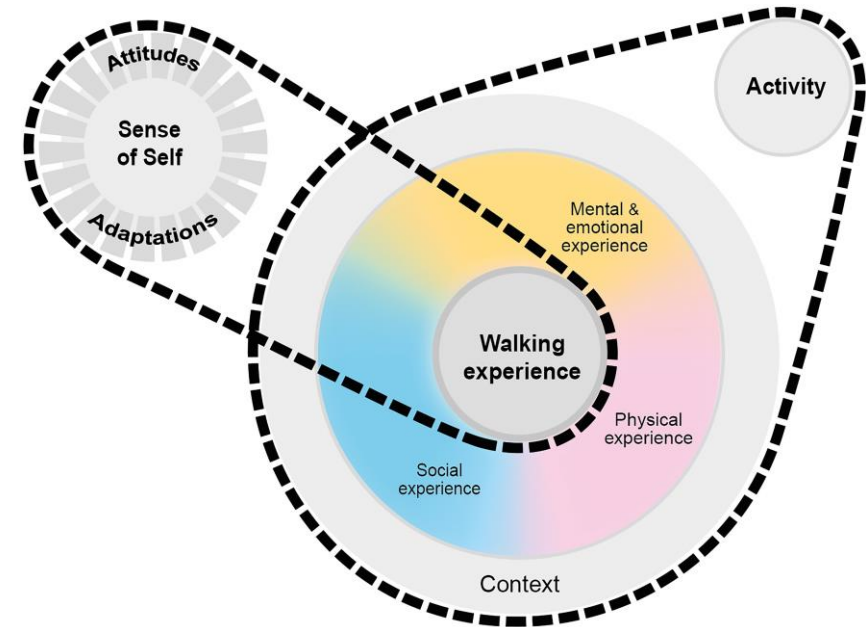
rettpfdd.org

Foundational work in developing new evidence tools

Putting it into practice!



DDT COA #00173: MEADOW-RETT-BR



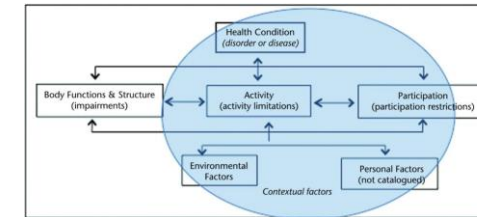
[Listening to the patients' voice: a conceptual framework of the walking experience | Age and Ageing | Oxford Academic \(oup.com\)](https://academic.oup.com/ageandageing/article/47/1/1/5544444)

What must we measure?

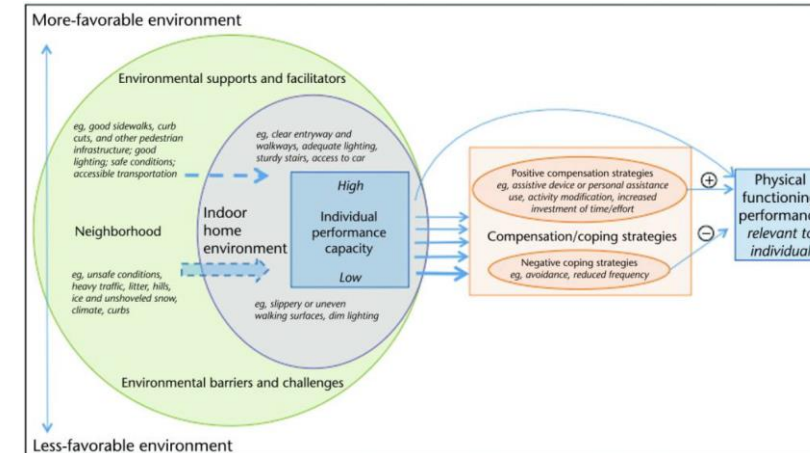
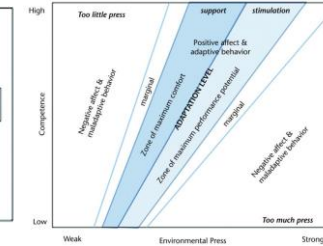
Progress towards (some) key remaining challenges: multi-sensors and context



WHO ICF model



Environmental press



PF/E model

- [Remote health & wellness with mSafety from Sony \(sonynetwork.com\)](https://sonynetwork.com)
- [ActiGraph LEAP | ActiGraph Wearable Devices \(theactigraph.com\)](https://theactigraph.com)
- [Introducing Verily Study Watch | Verily | Alphabet Precision Health Company](https://www.verily.com)
- [EmbracePlus | The world's most advanced smartwatch for continuous health monitoring \(empatica.com\)](https://empatica.com)

[Assessment of Physical Functioning: A Conceptual Model Encompassing Environmental Factors and Individual Compensation Strategies - PMC \(nih.gov\)](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4111111/)

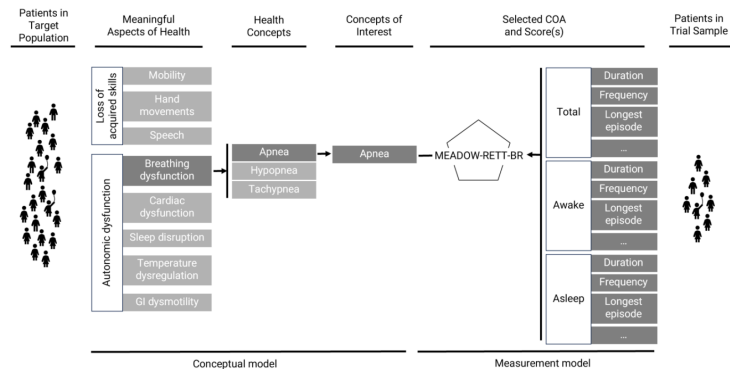
What must we measure?

Progress towards (some) key remaining challenges: regulatory progress and pathways

Clinical Outcome Assessments (COA) Qualification Program
DDT COA #TBD: Meaningful Ecological Assessment Derived from
Wearables – RETT syndrome - BReathing dysfunction (MEADOW-
RETT-BR)
Letter of Intent

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Consortium partners

Newcastle University, The University of Sheffield, CJAU, KU LEUVEN, EPFL, FAU, UCD, NTNU, R3K, uniss, ISGlobal, Imperial College London, University of Zurich, Universitätsklinikum Erlangen, pri, CHU, Xcient, mcroberts, AMGEN, AstraZeneca, BAYER, ERT, GRÜNENTHAL, ICON, Merck KGaA, NOVARTIS, Pfizer, Takeda, teva



Thank you

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