

# Common Terminology in Digital Health Clinical Investigations

## TERM DEFINITION

Clinical  
outcome  
assessment  
(COA)

Assessment of a clinical outcome that can be made through report by a clinician, a patient, or a non-clinician observer or through a performance-based assessment

Durable  
electronic  
data  
repository

An enduring database that is electronically protected from alterations and is maintained until the end of the record retention period

Context of  
use

A description of how the medical product development tool is to be used, including applicable regulations and review-related purpose of the use

Fit-for-  
purpose

A conclusion that the level of validation associated with a digital health technology is sufficient to support its context of use

Usability  
studies

Studies conducted to demonstrate that the digital health technology can be used as intended by the intended trial population, without serious errors or problems

Validation

Confirmation by examination and provision of objective evidence that the selected digital health technology appropriately assesses the clinical event or characteristic in the proposed participant population

Verification

Confirmation by examination and provision of objective evidence that the physical parameter that the digital health technology measures (e.g., acceleration, temperature, pressure) is measured accurately and precisely over time

Patient-  
reported  
outcomes  
(PROs)

A type of COA that is based on a report that comes directly from the patient regarding the status of the patient's health condition without amendment or interpretation of the patient's response by a clinician or anyone else. Can self-reported or by interview

Performance  
outcome  
(PerfO)

A type of COA that is based on standardized task(s) actively undertaken by a patient according to a set of instructions. May be administered by a trained individual or completed by the patient independently



# Examples of Potential Health Digital Technology Used in Clinical Investigations

## Sensor-based Hardware

**Evaluation of a novel orthotic device to treat knee osteoarthritis.** The clinical investigation uses a general-purpose consumer activity tracker to measure step-count.

DHT	General-purpose consumer activity tracker bracelet
DHT Hardware	General-purpose consumer activity tracker bracelet w/ sensors
DHT Software	None
General purpose computing program	None
Purpose of using DHT	Measure a patient's steps during a clinical investigation as part of the endpoint of interest

## Software

**Evaluation of a drug to treat symptoms of Alzheimer's disease.** Participants perform a clinical outcome assessment memory task on their phone during the clinical investigation.

DHT	Memory task mobile application
DHT Hardware	None
DHT Software	Memory task mobile application
General purpose computing program	Smartphone
Purpose of using DHT	Measure a participant's active performance on a memory task during the clinical investigation as part of the endpoint of interest. Send a reminder to the participant to complete the memory task.

## Sensor-based Hardware

**Evaluation of a drug for the management of Type 2 Diabetes.** The clinical investigation uses an FDA-cleared continuous glucose monitor device to track hypoglycemic episodes.

DHT	FDA-cleared continuous glucose monitor device w/ mobile app.
DHT Hardware	FDA-cleared continuous glucose monitor sensor- uses mobile app.
DHT Software	Mobile app. that serves as the interface and provides analysis/ alarms
General purpose computing program	Smartphone or tablet (the mobile app. is compatible with multiple platforms)
Purpose of using DHT	Continuously measure glucose levels in the body during the clinical investigation as part of the endpoint of interest

& Software

## Multiple DHTs

**Evaluation of a medical product to treat pulmonary disease.** Multiple DHTs are used during the clinical investigation to measure different aspects of the participant's functioning at home.

DHT	1. FDA-cleared spirometer with smart connectivity 2. General-purpose consumer activity tracker bracelet 3. Mobile app. where participants rate their perceived functioning each day
DHT Hardware	1. FDA-cleared spirometer with smart connectivity 2. General-purpose consumer activity tracker bracelet
DHT Software	3. Mobile app. - participants rate their perceived daily functioning
General purpose computing program	Smartphone or tablet (the mobile app. is compatible with multiple platforms)
Purpose of using DHT	Measure a participant's daily functioning and related metrics longitudinally in the participant's home environment during the clinical investigation as part of the endpoint of interest

## DHTs Summary

**Evaluation of a medical treatment to treat insomnia.** A DHT is used during the clinical investigation to measure multiple step parameters while participants sleep at home.

DHT	Portable wearable device that has received FDA marketing authorization
DHT Hardware	Portable wearable device that has received FDA marketing authorization
DHT Software	None
General purpose computing program	None
Purpose of using DHT	Remotely measure a participant's sleep parameters during the clinical investigation as part of the endpoint of interest.