Metadata standards to support deployment of Digital Health Technologies in Clinical Trials in Parkinson's Disease

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Objective:

A metadata framework for Digital Health Technologies (DHTs) to support enhanced regulatory maturity, and to facilitate standardization and harmonization of data collection.

Background:

DHTs could complement traditional clinical assessments in PD through high-frequency data collection, greater accuracy, improved objectivity, and capturing fluctuating symptoms and occasional events e.g.: freezing of gait. But poor comparability of data from DHTs (e.g., between devices, between studies) is a barrier to widespread adoption and regulatory acceptability.

Method:

A metadata standard to support harmonization of data from DHTs needs to describe the *devices* themselves (e.g., wrist-worn accelerometers) as well as how they are used to study a *concept of interest (COI)* (e.g., gait speed in a patient with Parkinson's disease). We reviewed existing metadata approaches and their implementation, and considered a pragmatic framework for clinical trial use comprising:
(a) metadata that is *independent* of the COI
(b) metadata that is *dependent* on the COI

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Results:

The framework is illustrated below.

The **COI independent** metadata is quite generic – and can be used to describe data collected for many COIs e.g.: an accelerometer could be used to measure many different parameters in various patient populations, including total activity, gait speed, turning gait, falls, sleep, and tremor. For all these applications, there is an additional need for **COI-dependent** metadata to complement this core. The framework illustrated below has been applied to several use cases

We have applied the framework to data collected with APDM sensors and Apple Watch sensors within the WATCH-PD clinical study (NCT03681015)
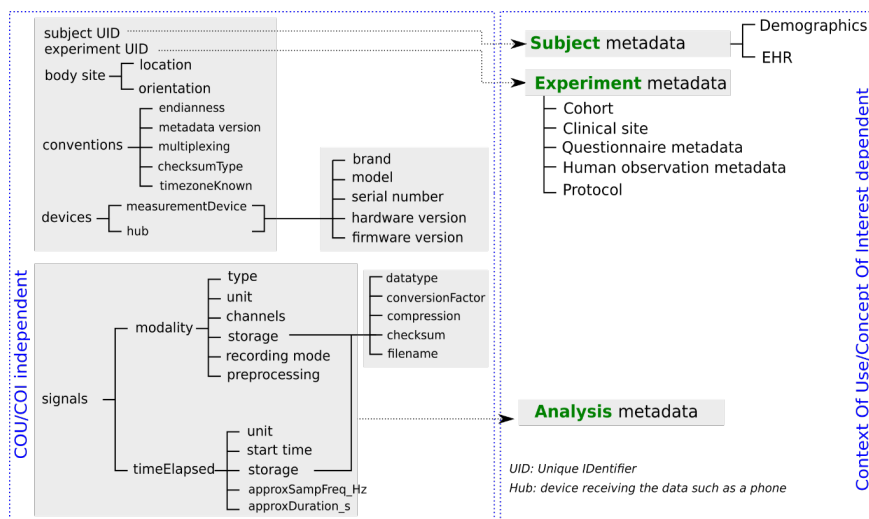
Metadata Framework:

UID: Unique IDentifier
Hub: device receiving the data such as a phone

Key innovations:

Flexible implementation: Recognizes that individual devices are used in many different trial designs.

Supports pre-specification: Required metadata values for a particular study are specified *a priori*. In this way, the metadata framework helps define how it should be collected and enable quality assurance of that data collection, supporting standardization across trials.

Helps control sources of variability: The metadata captures hardware/software differences that may lead to variability but can also capture environmental factors that may contribute to variability, e.g.: ambient temperature, location in the home, presence of caregiver can also be incorporated where these are known.

Conclusions:

The proposed metadata framework achieves three goals:
1. It captures the minimum core information we need to record about DHTs data collection to optimize the value of the derived measures and control the variability that can arise if this information is not captured.
2. It supports the comparison of measures of the same COI using different DHTs (such as APDM sensors and Apple sensors in the example given above), helping us move towards a device-agnostic approach to the measurement of a given COU.
3. Through the use of pre-specification, it provides a means to standardize, and quality assure collected DHTs data and is a step forward toward harmonization of data collection across devices and studies.