



Digital Biomarkers

A paradigm shift?



Digital Biomarkers

1. Definition
2. Digital clinical trials: creating a new publishing ecosystem
3. Paradigm shift in validation?
4. FAIR Data and services
5. Open access / Open science / (Meta)Data-sharing
6. Conclusions or more questions?



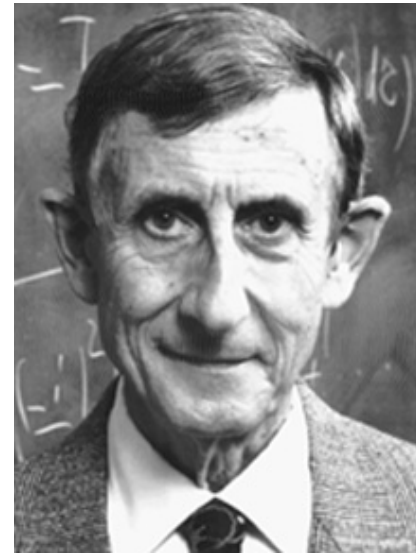
Definition

“...Imaging and genetics have revolutionized our understanding of health...Digital Biomarkers – objective, quantifiable measures of biology or health collected and measured through digital devices – can do the same.”

Scientific progress results from the development of new tools

“New directions in science are launched by new tools much more often than by new concepts ... The effect of a tool-driven revolution is to discover new things that have to be explained.”

Freeman Dyson (1997)



Imagined Worlds
Harvard University Press,
Cambridge, MA

Digital Biomarkers

The Ecosystem @ Karger



Prof. E. Ray Dorsey, MD
Rochester, NY, USA

Editor-in-Chief

Conferences

- Digital Biomarkers Conference Roche June 2019
- DayOne Conference, Basel September 2019



Digital Medicine Society

Bottom-up creation of a community of MD's with their specialisation who are also computer scientists, data specialists and or electrical engineers and who are either in academia or industry

Launch of the society: June 2019

<http://dimesociety.org>

Society

Platform



MEDICT – Metadata of Digital
Clinical Trials Platform



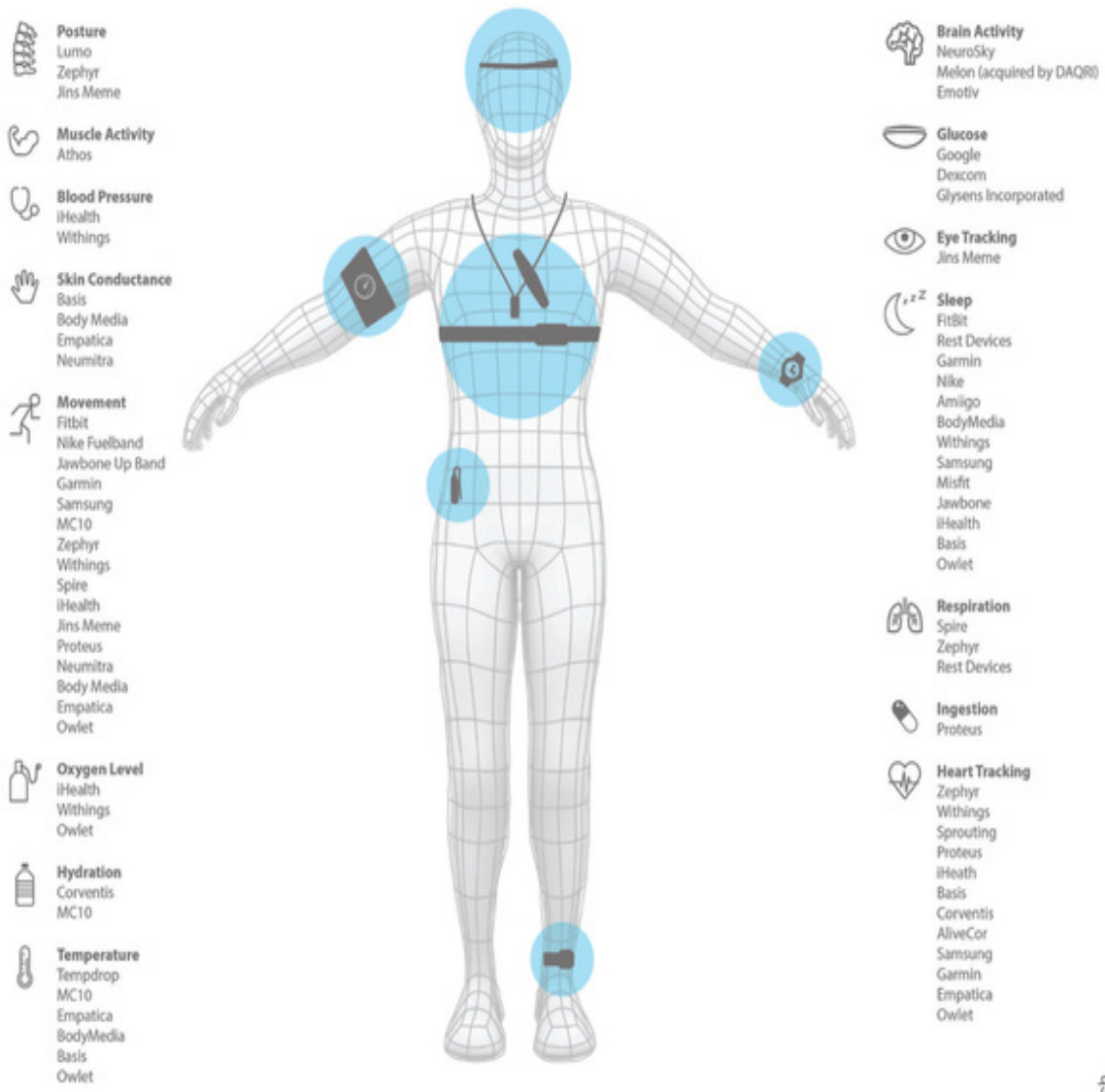
Paradigm shift in validation?

1. Back to the future?
2. New tools?
3. Datasets
4. Data analysis
5. Data tools: devices

Future trials will incorporate new tools that transform clinical trials

Characteristics of 20th vs 21st century clinical trials

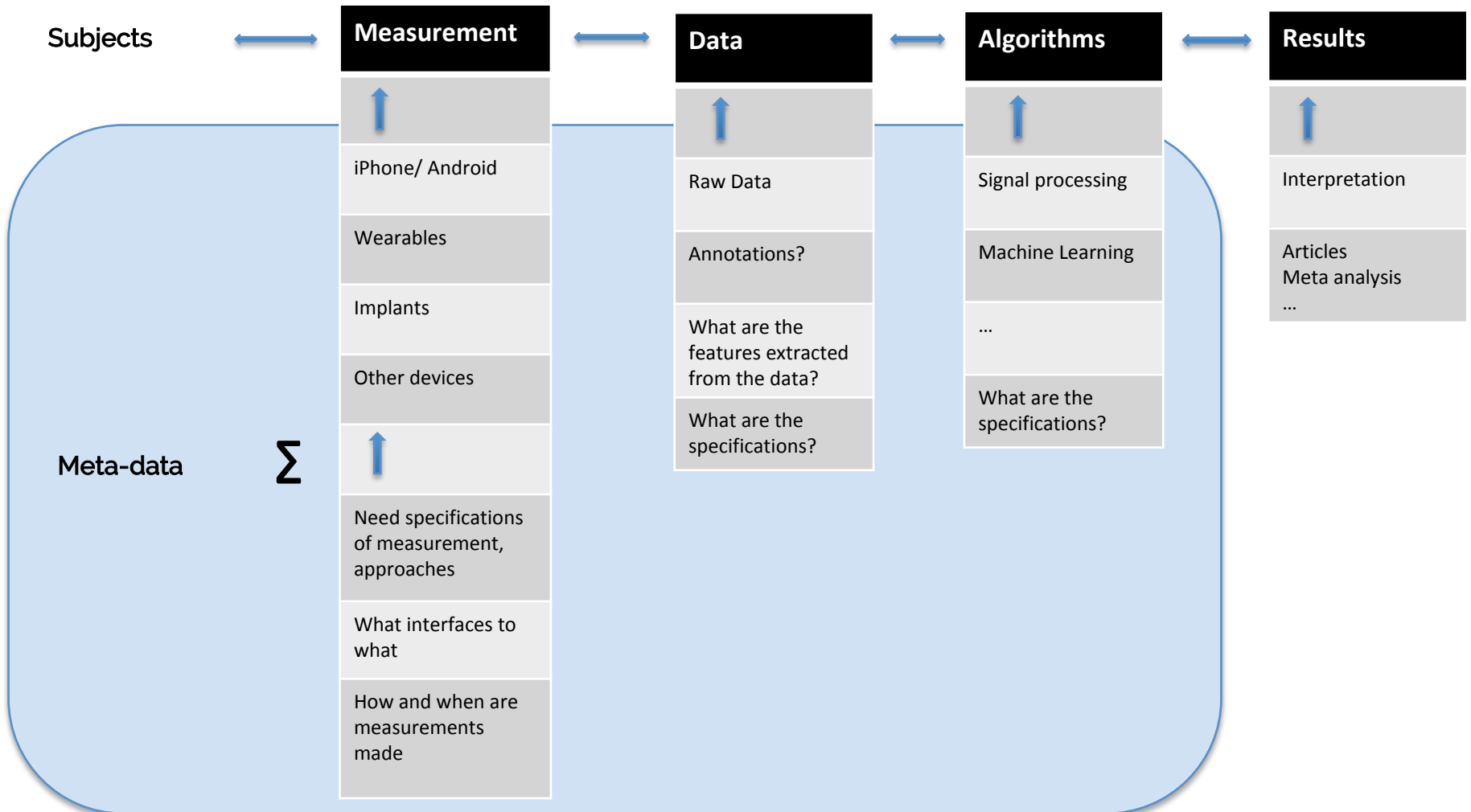
Characteristic	20th Century	21st Century
Study design	Randomized, double-blind, parallel-group, placebo-controlled trial	Randomized, double-blind, parallel-group, placebo-controlled trial using adaptive designs
Study population	All comers with a given disease	Individuals selected based on phenotypic and genetic results
Study recruitment	Clinical practices	Global clinical trial registries and social networks organized by individuals affected by the disease
Trial visits	In person and audio calls	In person and audio and video calls
Data management	Paper and electronic forms	Electronic forms
Participant feedback	Limited, delayed	Almost universal, approximately real time
Outcome measures	Insensitive	Sensitive
	Episodic	Frequent or continuous
	Subjective	Objective
	Provider centered	Patient centered
	In clinic	Remote
	Unidimensional	Multidimensional



* This is not a comprehensive list

PureTech

Digital Biomarkers: Sensor / Signal / Datachain





FAIR Data & Services

FAIR Data and Services

Status quo: Datasets for clinical trials are not FAIR yet. DOI's for datasets do not exist yet. Finding all datasets on a specific topic is now not guaranteed. Neither is it known: how, what, when, who, why and for what a dataset was created.

FINDABLE: Making datasets for digital clinical trials findable and accessible is the first step in the process.

ACCESS: Datasets are stored somewhere and have an owner and administrator. Creating the links to this is first priority.

ACCESS: Means not free access to the data but access to the contact points to the data.

INTEROPERABLE AND RESUABLE: Creating a standard for metadata across the therapeutic areas will enhance the Interoperability and Re-usability of data.

The I and R in FAIR data is the biggest challenge?



Open access / Open science / (Meta)Data-sharing

The future of (applied) science (In my opinion)

Multidisciplinarity and therefore complexity (not complex) is the principle.

Open access: The future of scientific communication is based on open access

Open science: Without open science there cannot be open access either. Sharing data, software, creating connectable systems.

Data-sharing: Sharing raw data of citizens / patients is only possible under very strict conditions. But sharing metadata is possible.



Questions or conclusions?

Definition of “digital biomarkers” is it different from “biomarkers”

What’s new about the ecosystem

What’s new about 21st century “digital clinical trials”

What’s new about FAIR?

Isn’t it all about semantics – getting all stakeholders around the table and decide on a language and definitions?

Do we need more standards?