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# DHT Data Standard Subteam: A Path to Data Standardization of DHTs

Presented by Zahra Karimaddini, Data Science Product Leader, Roche

# Meet the Speaker

## Zahra Karimaddini

Title: Data Science Product Leader

Organization: F. Hoffmann-La Roche AG

Zahra Karimaddini, PhD, has a background in computational biology, data science and personalized medicine. Zahra received her PhD in Computation Biology and Bioinformatics from ETH Zürich, with a focus on applied mathematics in neural development. Later she joint Roche as a postdoctoral researcher with a focus on machine learning in cancer biology. Since 2020 she has worked as Data Standards and Governance Specialist at Roche. In this role she is working on development and enhancement of various nonCRF data models, including digital measures, that collect clinical trial data F.A.I.R.ly and regulatory compliant.
In addition to her work at Roche, Zahra is recently leading the Digital Health Technology (DHT) subteam at CDISC to develop data standards for using DHTs in clinical trials.

# Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

- *Zahra Karimaddini is both an employee and a shareholder of F. Hoffmann-La Roche AG.*

# Agenda

1. Introduction on DHT Usage in the Clinical Trials
2. Health Authorities Guidances
3. DHT Data Standard Challenges
4. Data Standardization of DHTs
5. CDISC DHT Subteam Scope

# Introduction on DHT Usage in the Clinical Trials

# Diversity of DHTs

DHTs are defined as an electronic method, system, product, or process that generates, stores, displays, processes and/or uses data within a healthcare setting [EFPIA].

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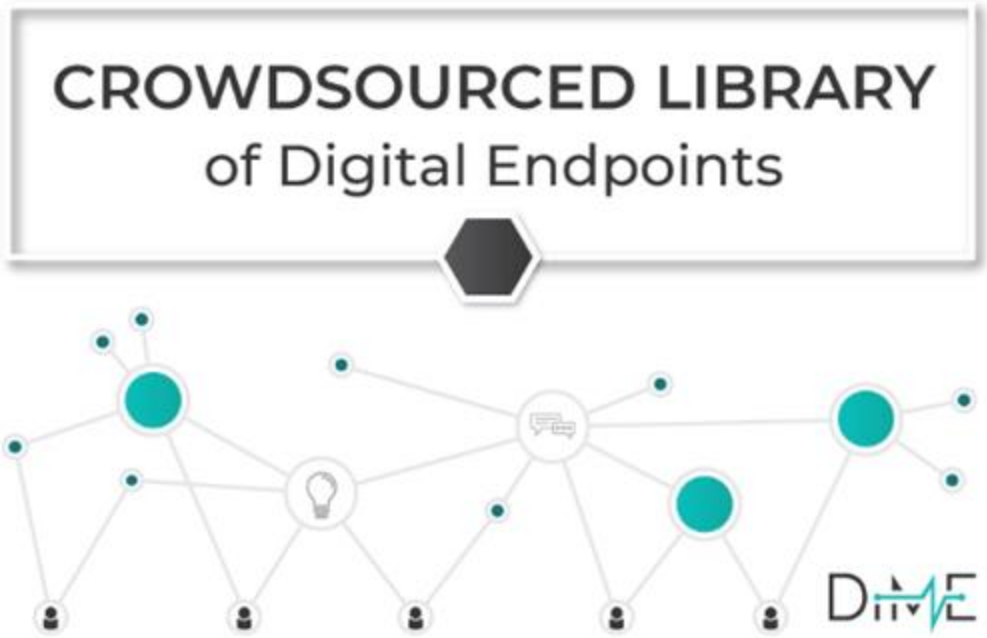
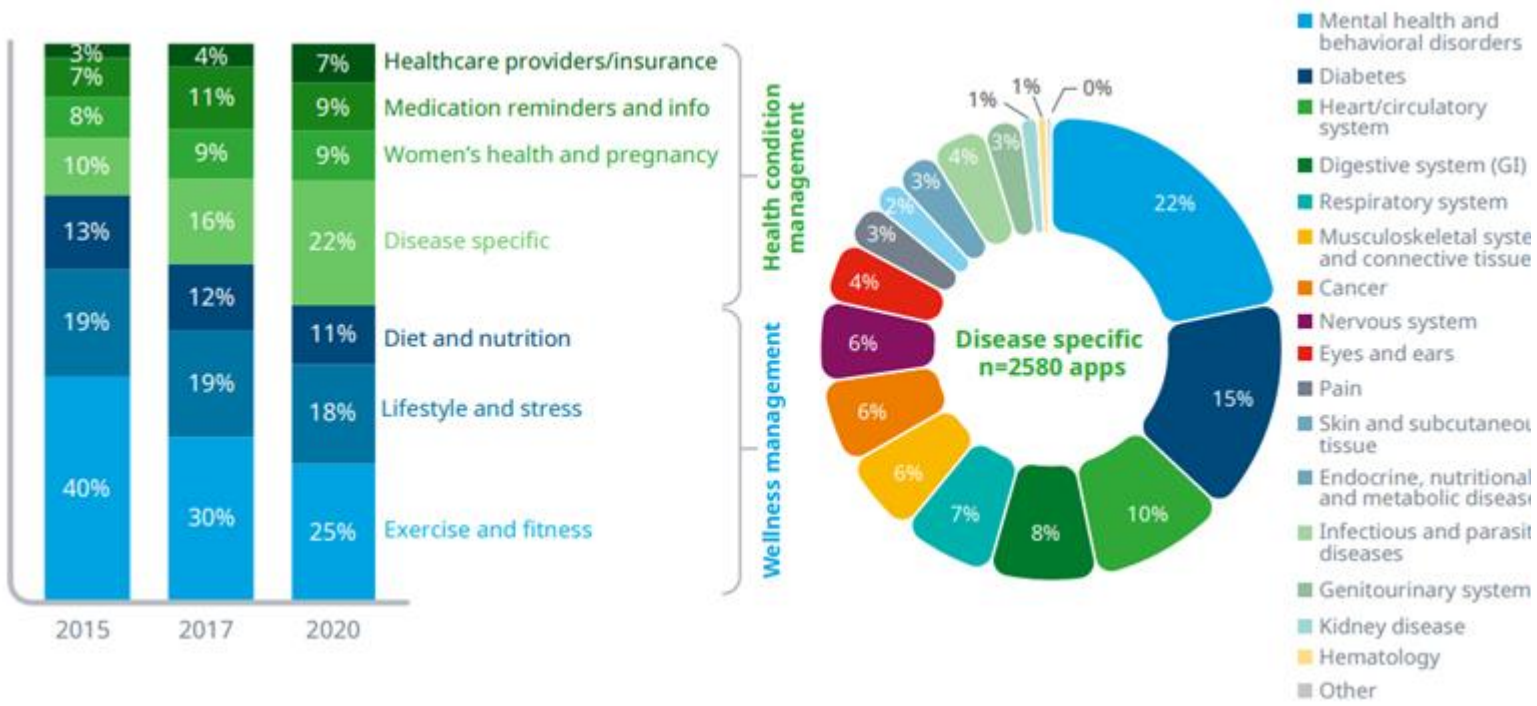
# DHTs in Clinical Trials

378 unique digital endpoints are currently being used by 104 sponsors across a wide range of therapeutic areas



# DHTs in Clinical Trials

IQVIA Digital Health Trends 2021
Digital Health Apps by Category and Disease State in 2021

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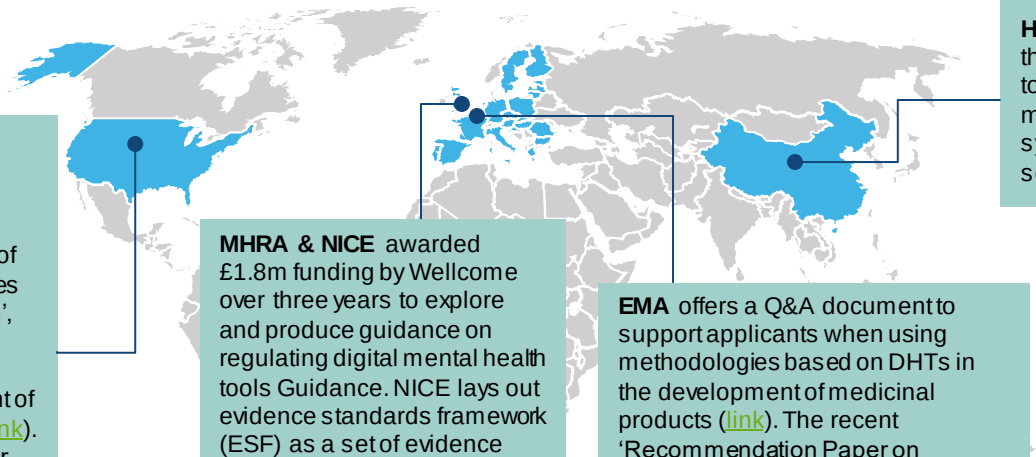
# Health Authorities Guidances

# Regulatory Landscape

## Governments and regulators across the world are increasing their focus on DHTs

### Selected Governments and Regulatory Initiatives Related to DHTs



**FDA DHTs** guidance outlines recommendations intended to facilitate the use of DHTs in a clinical investigation as appropriate for the evaluation of medical products. This includes guidance related to 'selection', 'verification', 'validation' and 'usage' of DHTs, as well as identification and management of risks associated with DHTs (link). Please refer to ' Framework for the Use of Digital Health Technologies in Drug and Biological Product Development' for the list of other published or planned documents by FDA (link)

**MHRA & NICE** awarded £1.8m funding by Wellcome over three years to explore and produce guidance on regulating digital mental health tools Guidance. NICE lays out evidence standards framework (ESF) as a set of evidence standards for a wide range of DHTs. ESFs includes standards related to the 'design factors', 'describing value', 'demonstrating performance', 'delivering values' development considerations' (link).

**EMA** offers a Q&A document to support applicants when using methodologies based on DHTs in the development of medicinal products (link). The recent 'Recommendation Paper on Decentralised Elements In Clinical Trials' covers importants aspects such as 'rules' and 'responsibilities' and 'data collection' and 'management' when a digital tool is used (link).

**Healthy China 2030 Plan** lays out the importance of digital health care to accelerate the establishment of a multi-dimensional medical security system and an integrated healthcare service system (link).

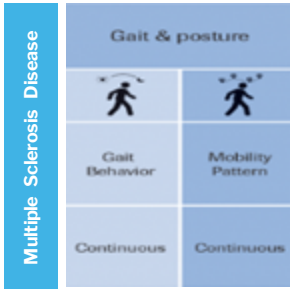
**WHO Global Strategy on Digital Health 2020-2025** lays out guiding principles with the aim to orient the global strategy towards the appropriate and sustainable adoption of digital health technologies within the context of national health sector and health strategies to encourage cooperation between and among stakeholders from both developed and developing countries (link).

# DHT Data Standard Challenges

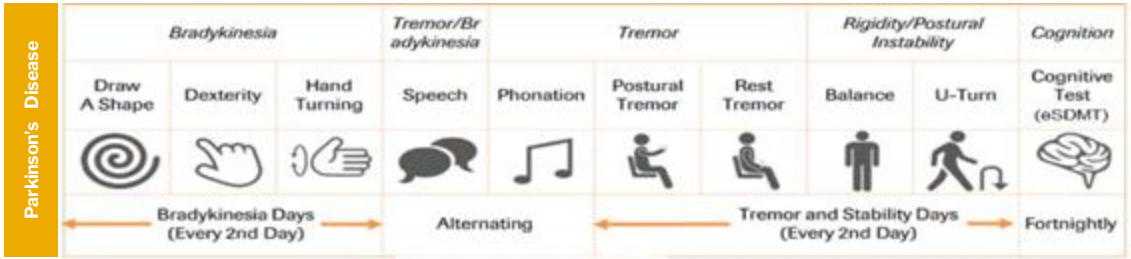
# Use Case Studies

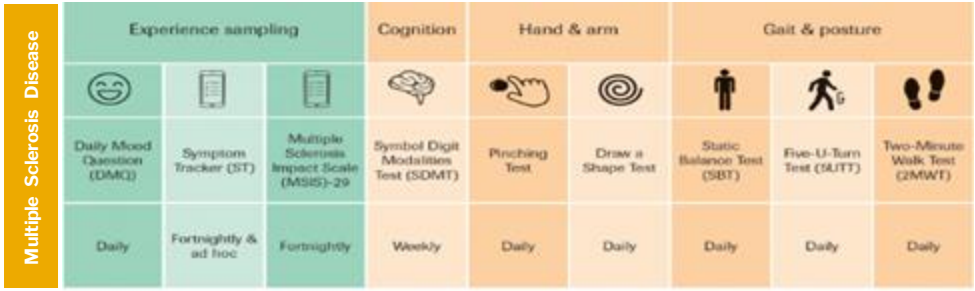
## Challenges of Data Standardization of DHTs across different disease areas

### Passive Monitoring


### Active Testing

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# Use Case Studies

## Challenges of Data Standardization of DHTs across different disease areas

### Challenges

- DHTs produce a wealth of data, but there is ambiguity in where and how the data will be accessed, transformed and collected in clinical trial.
- Previously, data was manually collected per study and not standardized across trials.

### Opportunities

- Data standardization enables to efficiently scaling up the integration and analysis of data:
  - compliant with health authorities requirements.
  - in conjunction with other clinical data and ready for secondary usage.

# Data Standardization of DHTs

# DHT Data Lifecycle in Clinical Trials

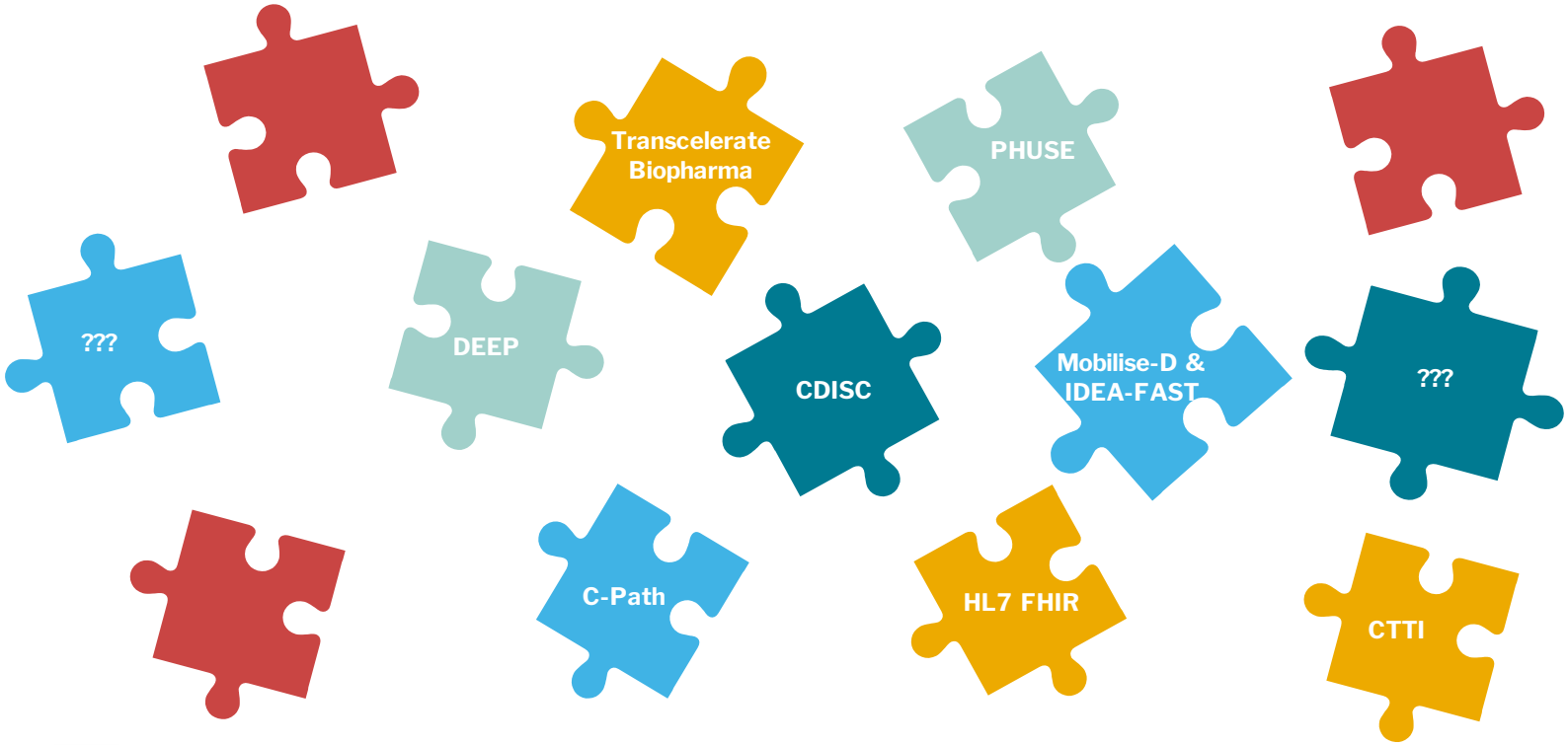
## Data standards for DHT data are required across the clinical trial data lifecycle

| Data Generation | Data Exchange | Data Tabulation | Data Analysis | Regulatory Submission |
|---|---|---|---|---|
| **Raw sensor data** often millisecond (e.g., touch event from device screen, accelerometers from sensors, etc.) & **metadata** (e.g., device data) | Data transferred to the Cloud, **feature data** calculated (summarizing information in **raw sensor data**) in lower resolution. | **Feature data** and associated **metadata** are tabulated. | **Feature data** analyzed (alone or in combination with other clinical trial data) and **digital endpoints** derived | **DHT data package** (tabulated & analysis-ready) submitted to health authorities*. |


* Supplementary documents including verification and validation of device, analytical algorithms, etc should be submitted separately.

# CDISC DHT Subteam Scope

# Industry landscape



# Proposed Scope: Phase 1

**Phase 1**

Identifying domain(s) for the most commonly generated measurements from passive monitoring and active tests

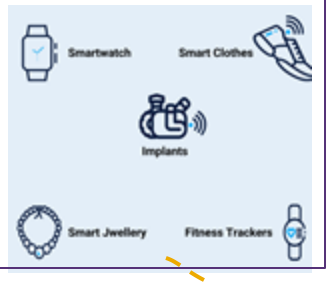
DHT Examples

ECG Monitoring source of image

Sleep Trackers source of image


Glucose Trackers source of image


Physical Activity Trackers source of image




Functional Tests Trackers source of image

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Some of CDISC Findings Observation Class

# Proposed Scope: Phase 1

| Phase 1 |
| --- |
| Identifying domain(s) for the most commonly generated measurements from passive monitoring and active tests |
| Defining Controlled Terminologies and Codetable Mapping Files for the most commonly used digital endpoints |
| Adoptionaption of SDTMIG for Medical Device (DI, DU, DX) to accommodate DHT needs >>> already drafted by MDIG team and is on the way!!! |
| Collaboration with cross-industrial DHT initiatives |
| Release the first draft of implementation recommendation for Public Review |

# Proposed Scope: Phase 2

| Phase 2 |
| --- |
| Expand the controlled terminologies and Codetable Mapping for the most commonly used and validated features |
| Incorporate HL7 FHIR potentials |
| Identification of potential needs for future CDISC standards development |

# Call for Volunteers

# CDISC Sub-team Seeks Volunteers

**Required Skills**

- A CDISC standards practitioner. Solid implementation experience with SEND, SDTM, and/or ADaM.
- Medical devices expert
- QRS domain expert

**How to Participate**

We invite you to participate in this exciting and fast-evolving new project

Please visit the CDISC Subteam Page (Participate tab) to learn more (link).

# Thank You!