DiMe Library of Digital Endpoints: Strengths, Weaknesses, and Pathways for Improvement in Digital Health Research

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Background: Access to a shared knowledge platform that provides validated, current, and comprehensive information on Digital Health Technology (DHT) is crucial for dissemination of innovation in this field. The DiMe Library of Digital endpoints is the first industry-focused, crowdsourced database for novel medical products and applications, excluding feasibility studies of digital measures. We seek to examine its strengths and weaknesses, using the NIH ClinicalTrials.gov database as cross-reference, and propose pathways for improvement.

Methodology: We conducted a comprehensive review of data from the DiMe Library, ensuring accuracy through rigorous verification and cross-checking with the NIH ClinicalTrials.gov database. For the DiMe library, we evaluated the whole dataset, which included digital endpoints from studies listed between January 2005 and April 2023 (**389 endpoints**), while for ClinicalTrials.gov the search criteria included *"wearable"* and other sensor-based terms (e.g., "*device*", "*digital*, "*actigraphy*", "accelerometer", "*smartwatch*", "*sensor*", etc.).

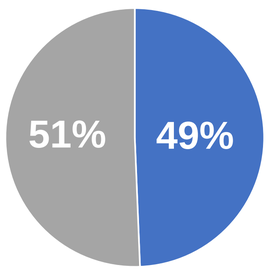


Fig. 1: Distribution of digital endpoints with missing device information.

Completeness

- 192 out of 389 digital endpoints (**49%**) were **missing key information** such as the name of the device used in the clinical study (Figure 1).
- When compared to trials registered in ClinicalTrials.gov over the same timeframe, **the DiMe library listed fewer digital endpoints**, but **more extensive details** were provided on the devices used and the concepts being assessed.

Supporting data

- Supporting documents regarding publications help to better understand the role of the digital device within the clinical study.
- Only 2 of 389 digital endpoints included publications or additional supporting documents.
- Important information such as the study protocol, summary of scientific results, device technical specifications are not available.

Strengths

- First crowdsourced library
- Dashboard (including distribution of endpoint positioning, study phases, and investigational products)
- Free information on digital endpoints

Weaknesses

- Missingness on key information
- Lack of supporting documents
- No data validation process
- DiMe ontology NOT implemented

Updates

- Regarding frequency of scheduled updates on the DiMe Library, the only available information is that the data is "*subject to both regular and sporadic updates*"
- The last big update was performed at the beginning of 2023, with major improvements, like the removal of digital endpoints with missing source information, and correction of typos.
- On the other hand, the NIH ClinicalTrials.gov database gives 30 days as a deadline for updating most of the studies, with exception of studies using a device product not approved or cleared by U.S. FDA, which is 15 calendar days. ClinicalTrials.gov also received a big update at the beginning of 2023, modernizing the platform.

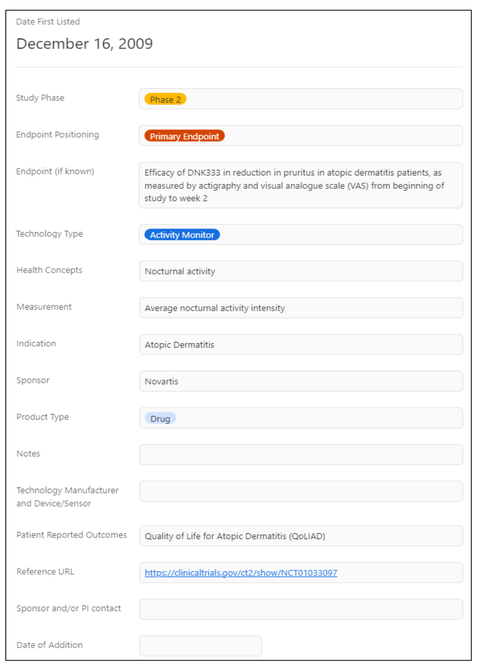
Accuracy of information

We identified different types of issues:

- Inaccuracies in reporting of the assessed concepts
- Reference from ClinicalTrials.gov missing the assigned digital endpoint reported in the DiMe library
- Minor wording inconsistencies

Data verification

- Currently, the DiMe library has minimal validation process for crowd-sourced data, as this information is not reported within the database
- On the contrary, ClinicalTrials.gov automatically detects some data entry issues when each module is saved.
- If the errors are not addressed, it may lead to issues during the data review process.



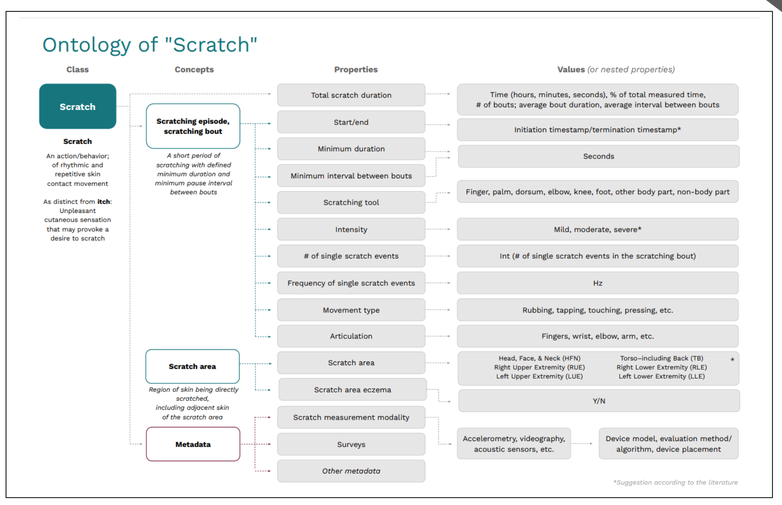


Fig. 2A (left): The digital endpoint entry from December 16, 2009.
Fig. 2B (right): The nocturnal scratch measure ontology developed by DiMe.

Ontology

- Over the past years, the Digital Medicine Society have been engaged in driving scientific progress throughout the development of many resources for different stakeholders, including a shared terminology and measure ontology in different key areas such as Alzheimer's disease and related dementia, nocturnal scratch, sleep disturbances, and physical activity.
- This powerful resource is not used in the Library of Digital Endpoints.
- For example, in Figure 2, the digital endpoint entry (**Figure 2A**), is clearly a nocturnal scratch measure in atopic dermatitis, but the ontology developed by DiMe on this concept is not reported anywhere in the digital library (**Figure 2B**).

Conclusions

The DiMe Library of digital endpoints is a powerful tool, providing relevant information on digital health technology. To enhance the impact of this key resource, a clear and strict **data review process** is needed to ensure **accuracy and consistency** within the dataset. An automated process to detect **missing data entries** or **errors** during this process could be a good help. The inclusion of additional **supporting documents** would be beneficial to improve the completeness of the information available on the digital endpoints.
C**ollaboration between device/tech companies** and **other stakeholders** can improve access to valuable information in this rapidly evolving field.