Background

The general public and collective biomedical research enterprise are increasingly embracing local and remote monitoring technologies, mobile smartphone apps, and portable/wearable devices into their activities of daily living. Many view these devices as future path to provide a deeper understanding of disease processes, patients’ cognitive and functional status, and quality-of-life assessments. Biometric Monitoring Devices (BMDs) refer to the use of a biosensor to continuously collect objective data on a biological recognition element (glucose, hormone levels, etc.), integrated physiological parameters (blood pressure, mobility/motor, memory/processing, speech/sleep patterns, social engagement, etc.). BMDs utilize algorithms to transform data into a format that is interpretable as a specific measure, or an aggregate functional outcome. Health platforms using BMDs are providing clinicians real-time evidence that allows efficient and continuous collection of data and assessments to monitor clinically meaningful parameters. The lack of clarity regarding the appropriate use of BMDs as Drug Development Tools to support drug registration trials was recently underscored by the newly appointed Commissioner of the FDA, Dr. Scott Gottlieb’s June 15, 2017, blog: “Fostering Medical Innovation: A Plan for Digital Health Devices” (Ref. 1).

Methods

The Coalition Against Major Diseases (CAMD) is a non-profit coalition at the Critical Path Institute. In the rapidly-evolving space of BMD utilization (Figure 1), CAMD convened diverse stakeholders, academia, regulatory agencies, and emerging technology companies, to explore the landscape of monitoring devices (BMDs) that can accelerate the drug development process. CAMD conducted a landscape analysis of BMDs utilized in assessing cognition, sleep, and mobility in Alzheimer disease (AD) and other age-related neurological diseases (Figure 2).

Results

• CAMD convened workshops to gather and unify the research community, subject-matter experts, device developers, standard development organizations, and regulators around the identification of existing gaps and challenges.

• CAMD performed a landscape assessment of the evolving digital space (Table 1), with a focus on:
  - Pre-clinical coordination/collaboration with key organizations;
  - Creation of a common lexicon and information dissemination (Ref. 2);
  - Assessments of existing devices in use;
  - Regulatory-science-based planning of use-cases for potential integration into clinical trial tools and a regulatory pathway across neurological diseases.

• BMDs represent a paradigm shift in evidence of biomarker changes or clinical endpoints for clinical trials.

• An innovative approach to data standardization across concepts-of-interest in neurodegenerative diseases (Figure 3), data integration, data analytics, and result validation is required.

Conclusion

• BMDs are promising, but as yet unknown, DDTs to advance innovative treatments for various stages of AD and other neurodegenerative diseases. A limitation of this initial survey is that it does not contain all the evolving technologies and approaches. This will be the focus of a future review.

• The volume and quality of studies of BMD data generation/validation/interpretation, the comparability among studies, and the pathway to overcome the challenges confronting the successful use and acceptance of BMDs for clinical research in CNS disorders will be improved, and the pathway to overcoming the challenges confronting the successful use and acceptance of BMDs for clinical research in CNS disorders will be improved.

• For additional FDA guidance on this topic see Ref. 3.

References


Table 1

Preliminary Landscape Survey of FDA-Cleared Devices and Devices Seeking FDA Approval

<table>
<thead>
<tr>
<th>Category</th>
<th>Device</th>
<th>Approval Status</th>
<th>Application</th>
<th>Age</th>
<th>Health Condition</th>
<th>Comorbidity</th>
<th>Indication</th>
<th>Use Case</th>
<th>Industry</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>COGNITION</td>
<td>Cognitron® (Central Nervous System-Cognitive Assessment Systems®)</td>
<td>FDA cleared</td>
<td>for specific case-use</td>
<td>up to 18 years</td>
<td>AD, PD, Schizophrenia, Depression, Epilepsy</td>
<td>no comorbid conditions</td>
<td>Assessments in clinical trials</td>
<td>Secure data transfer</td>
<td>DuraSenses, Inc.</td>
<td>Yes</td>
</tr>
<tr>
<td>SLEEP</td>
<td>SleepSight (Zmachine, TECH.)</td>
<td>FDA cleared</td>
<td>for specific case-use</td>
<td>up to 18 years</td>
<td>AD, PD, Schizophrenia, Depression, Epilepsy</td>
<td>no comorbid conditions</td>
<td>Assessments in clinical trials</td>
<td>Secure data transfer</td>
<td>MotionWatch, Ltd.</td>
<td>Yes</td>
</tr>
<tr>
<td>MOBILITY</td>
<td>UsAgainstAlzheimer’s (GAP)</td>
<td>FDA cleared</td>
<td>for specific case-use</td>
<td>up to 18 years</td>
<td>AD, PD, Schizophrenia, Depression, Epilepsy</td>
<td>no comorbid conditions</td>
<td>Assessments in clinical trials</td>
<td>Secure data transfer</td>
<td>UsAgainstAlzheimer’s</td>
<td>Yes</td>
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