mHealth in Clinical Trials

Instrumenting Patients with Sensors, Wearables & Apps

Clinical trial sponsors are struggling with how to realize the extraordinary potential mHealth has to offer. The explosion of sensors, in the form of wearables, smartphones and remote devices, coupled with powerful apps and pervasive wireless access, opens the door to rethinking the traditional model of study conduct.

While the possibilities associated with instrumenting patients are truly transformational, challenges abound:

- Device failure
- User error
- Not ready for BYOD
- Data integration
- Poor quality data
- Introduction of bias
- Privacy / security
- Regulatory compliance
- Site preparedness
- Etc...

Scaling is another challenge. For example, a recent mHealth initiative generated 18 million data points per patient per day. How do you manage data volumes on this scale? With many mHealth innovation projects already underway, demonstrating the value of the technology in a compliant, effective and safe way is critical; choosing an experienced partner is the key.

Medidata Experience

By equipping patients with smart devices, studies can capture real-world data in an unobtrusive way. This data is objective, it’s eSource and it complements site-captured data. Protocols can use cumulative measures for motion, heart rate, gait, body position, sleep time and events like tremors.

To realize this opportunity, Medidata has created an integrated clinical record that links mHealth data with traditional clinical data and, in doing so, presents the data in a seamless and easily consumable way. With the intelligent application of sophisticated data science techniques, sponsors can explore all the potential of mHealth in clinical development: rethinking study endpoints, better understanding disease progression and searching for digital biomarkers.

“This sector will be unrecognizable in five years”
– George Freeman, UK Minister for Life Science
Medidata’s experience in mHealth spans many studies across therapeutic areas, phases and geographies. For example, a joint initiative we conducted with GlaxoSmithKline exploring patient engagement, data quality and operational efficiencies was announced recently. This experience enables us to share not only technology, but also insights that help uncover real value: better data quality, improved patient experience and more efficient trials.

Medidata Commitment

Having led the industry to realize the benefits of cloud technology in the form of electronic data capture (EDC), Medidata is now driving the adoption of mobile technology. This commitment began with the introduction of our mobile app for patient-reported outcomes, Medidata Patient Cloud, and continues with our mHealth Closed Charter Program which enables sponsors and CROs to incorporate mHealth into their studies today**.

Furthermore, to expand our knowledge base, Medidata is sponsoring a trial focused on the use of mHealth technology, the MOVE diabetes trial. Successfully overcoming the many obstacles found in the adoption of mHealth requires close collaboration between the life sciences and technology industries. Medidata is the company that combines the discipline of clinical research with the promise of mHealth. As your technology partner, we’re committed to making your mHealth projects a success.

** For information about Medidata’s Closed Charter Program, please contact a Medidata representative.

Potentially expansion and improvement in endpoints

<table>
<thead>
<tr>
<th>Medical Condition</th>
<th>Old</th>
<th>New (from pharma sponsor feedback)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IBD / Crohn’s disease</td>
<td>Steroid-free remission</td>
<td>Geographic distance traveled from home</td>
</tr>
<tr>
<td>Stroke</td>
<td>NIHSS (National Institutes of Health Stroke Score) or Rankin Scale</td>
<td>Gait, cadence, balance of steps between left foot and right foot</td>
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<tr>
<td>Parkinson’s</td>
<td>Unified Parkinson’s Disease Rating Scale (UPDRS)</td>
<td>Level of vocal tremor during phone conversations</td>
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<tr>
<td>COPD</td>
<td>6-minute walk test</td>
<td>Daily steps for trial duration</td>
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<tr>
<td>Asthma</td>
<td>PRO surveys on number of night awakenings</td>
<td>Number of night awakenings detected by wearable device</td>
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<tr>
<td>Obesity</td>
<td>Weight, blood pressure and hypoglycemic events</td>
<td>Active minutes / steps walked</td>
</tr>
<tr>
<td>Rheumatoid arthritis</td>
<td>Count of swollen and tender joints</td>
<td>Active minutes / steps walked</td>
</tr>
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About Medidata

Medidata Solutions is the leading global provider of cloud-based solutions for clinical research in life sciences, transforming clinical development through its advanced applications and intelligent data analytics. The Medidata Clinical Cloud™ brings new levels of productivity and quality to the clinical testing of promising medical treatments, from study design and planning through execution, management and reporting. We are committed to advancing the competitive and scientific goals of global customers, which include over 90% of the top 25 global pharmaceutical companies; innovative biotech, diagnostic and device firms; leading academic medical centers; and contract research organizations.

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