Swimming in a Data Lake of eCOA Wearables

By Mark Wade, Global Practice Leader Life Sciences, TransPerfect

Human clinical trial studies have become increasingly complex, costly, and longer. In the last 20 years the pharmaceutical industry has seen the cost of studies, including compounds that either failed during a study or never made it out of Phase I, balloon to approximately 2.6b USD. Of the 1,442 compounds discovered and tested from 1995—2007, only 7.1% were approved and 80.3% were discontinued.[1]

Regardless of the reasons for such a high failure rate, it is clear that there is value in reducing that failure rate and reducing the cost associated with same. The volume of data that we are accumulating via electronic data capture (EDC), electronic clinical outcome assessments (eCOAs), and wearable devices is larger than ever. Consider how much data would be captured monitoring a patient 24/7. Consider annually over 254,787[2] studies in the United States alone with an average of (arbitrarily) 3,000 patients enrolled. The amount of data we are scheduled to capture is unparalleled. This data is currently housed in separate data silos but will need to be addressed in a federated approach to store data in various domains, e.g., IRT, eCOA. Each of these repositories will contain metadata that can be used together in dynamic analysis using smart algorithms.

According to Statista[2], the wearable devices market is currently having a worldwide revenue of around $26 billion, and is expected to reach almost $34 billion in 2019. Regarding healthcare and medical environments, it is expected to grow almost to $15 billion worldwide value in 2019.[7]

The analysis will get bigger, more complex, and become overwhelming for use in real-world evidence. This big data will unlock information that could change and suggest which studies will move forward and what studies can be terminated early, thus saving valuable time and money. The corollary is that this data will suggest studies that

may be fast-tracked. Where and how will the sponsor get the patients required? The potential for study streamline is obvious.

More than 16,000 hospitals today are collecting data on patients in a data pool where 80% of that data is unstructured. In the clinical trial arena almost 5m participants will provide remote monitoring data and that is expected to grow by 18% CAGR annually. Patient-monitoring equipment pumps out over 1,000 data points/readings per second. That's 90,000 readings per day, 33m readings per patient, per year.[3,4]

Wearables

The promise of leveraging sensors and wearable devices to gather vast amounts of data from a patient is a path to the Holy Grail for most sponsors. With the advent of large data sets, virtual clinical studies become more possible.[5] The benefit of fewer patient site visits maximizes the

patient recruitment pool. The patient recruitment bottleneck could be eased.[6]

Currently wearables are divided into four groups:

External Devices:
Physically separate from the user
- Movement detection camera
- Weighing scales
- Digital spirometer

Implantable Devices/Sensors:
Inserted into the human body
- Cardiac arrhythmia monitors
- Brain liquid pressure sensors

Wearable Devices/Sensors:
Integrated into clothing/accessories that are worn on the body
- Activity monitors
- Pulse oximeters
- Heart rate monitors

Ingestible Devices/Sensors:
Swallowed by the user, and data set sent to an external collection device
- Ingestible core temperature sensors
- Ingestible medication tags

Considerations

SAFETY

- Mechanical performance: Is the battery on the sensor designed to last the prescribed period?
- Electrical performance: Is the electrical device suitably shielded from outside elements?
- Biological engineering performance: Is the device inert? Will it impact the patient data?
- Is it compliant with electrical safety and electromagnetic standards?
- Sterility: Will it be prone to infection?
- Stability/shelf life: Is the device designed to last throughout the entire study?

SUITABILITY

- Study objectives: Does the sensor/device match the objectives of the study?
- Patient population: Is the sensor/device suitable for the targeted patient characteristics?
- Study design: Is the data secured and non-editable? Do we have real-time access to the data?

VENDOR CHARACTERISTICS

- 21 CFR part 11: Does the vendor have access and control of source data?
- Firmware: How will the firmware be updated? Who is responsible for support?
- Acquisition: What happens if the vendor is acquired or goes out of business?
- Device logistics: Who is responsible for deployment? For replacement?

Current Landscape

There are many products that monitor bio functions. Our cell phones track our footsteps, and other wearable devices monitor our heart rate and our sleep patterns. All of this data is extremely useful for a person looking to better their overall health, but these devices are not industry grade. We instinctively understand that companies that provide certain commercial services use machinery that is of a higher grade than what the average person would use (industry grade vs. consumer grade). Their equipment is more heavy-duty, more robustly tested, and typically has a longer life span.

The regulation pertaining to sensors for use in clinical trials, specifically for primary endpoint studies, is something that needs to be addressed.

CONSUMER GRADE

Intended Use: Recreational/individual only

- Regulations for medical devices do not apply
- No lock down design
- Manufacturing not GMP compliant
- Performance not verified
- Easy access and convenience of use
- Users can interpret and make decisions based on their data
- Software version control not validated
- Lifespan of device may not be suitable for certain longitudinal studies

COMMERCIAL GRADE

Intended Use: Diagnosis, disease prognosis or treatment decisions

- Approved/cleared by regulators
- PMA or 510K in the US lock down design
- Manufactured under GMP
- Established standardized performance
- Administered by HCP
- Results are usually interpreted by HCP
- IQ/QQ/PQ established if applicable

Discussion

The argument for electronic capture has been largely settled with the publishing of multiple metadata analyses in 2017 and 2018.[6,7] Before the dust has barely settled, we are on the cusp of introducing vast data sets via wearable sensors. Be it external, body wearable, implantable, or ingestible, each will download millions of data points per patient, per study. This big data has the potential to overwhelm a study team. Data scientists will be challenged with not only the mass of data but also the disparate systems that do not have universal interoperability, and 80% of that data will be unstructured. Much like during the internet boom, when there was an uptick of middleware software creation, the time is right for the creation of interoperability software that can parse the data from numerous Electronic Health Records (EHR) platforms.

The other consideration is whether or not devices that are used for data collection in clinical trials need to have a 510K license. We expect this for Class II products, so why would we accept at face value the data captured from an OTC consumer product?

References:

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3 IBM https://clinicaltrials.gov/ct2/resources/trends

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5 Virtual Clinical Trials: Challenges and Opportunities

6 A meta-analytic review of measurement equivalence study findings of the SF-36® and SF-12® Health Surveys across electronic modes compared to paper administration

7 Measurement Equivalence of Patient-Reported Outcome Measure Response Scale Types Collected Using Bring Your Own Device Compared to Paper and a Provisioned Device: Results of a Randomized Equivalence Trial