

A Leading Academic Medical Center Monitors Newly Diagnosed Myeloma Patients with Rave eCOA

The Challenges

When oncology patients are at the onset of treatment, they are faced with balancing the daunting reality of their condition with general quality of life. There is a direct correlation between a clinical outcome and factors such as sleep, physical fatigue, and mood disturbances. Doctors understand the interdependence between how patients are feeling and their health, and do their best to strike a balance between quality of life and disease control. When these balances are skewed, patients can be left with adverse outcomes such as increased toxicity or residual disease.

It is often difficult for oncologists to fully grasp the quality of life measure for a patient, because it encompasses so many dimensions of a patient's life including satisfaction, family, education and employment. However, tools have been developed to help measure these quality of life factors; these are known as PROs, or patient reported outcomes. A PRO allows a patient to report their quality of life independently of their oncologist, offering direct insight into the patient perspective. Although somewhat subjective, the patient reported outcomes offer validated and reliable tools across trials, and their use has been linked to improved outcomes in clinical practice.

Although patient reported outcomes offer several advantages, they have their drawbacks as well. PROs can be subject to underreporting or overreporting, and are often difficult to implement into clinical practice. Additionally, the use of a paper patient reported outcome system is cumbersome, can result in data or organizational errors. The consideration of these drawbacks led a leading academic medical center to consider the use electronic PROs, or ePROs in their study on electronic data capture in Multiple Myeloma patients.

The researchers sought an electronic platform which was convenient for their patients, while still offering objective measurements of quality of life data. To gain a comprehensive understanding of the lives of cancer patients outside of the chemo unit, they needed to combine the most advanced science with most advanced data-capture technology. Collaborating with Medidata in their expansion of Mobile Health (mHealth) technology in oncology treatment,

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partnered best in class clinical research with an advanced cloud-based ePRO solution. The innovative study included a clinical trial with 40 patients, split into 2 arms, to assess the quality of life of patients younger than 65 and 65 or older with myeloma.

The Solution

The researchers, using Medidata's cloud-based Rave Wearable Sensors solution, were able to analyze activity and sleep trends, identify outliers, and assess patient compliance and data quality. Patients wore activity trackers for 1-7 days before induction chemotherapy treatment to establish a baseline, then were monitored continuously up to completion of six cycles of chemotherapy.

The Medidata Rave eCOA app allowed patients to generate activity level, fatigue, and appetite data on their smartphones. Since the institution was already using Rave EDC as their clinical study platform, its ability to unify with Rave EDC to ingest, store, and summarize data within the Medidata Rave Clinical Cloud™ made it a great candidate for the study.

Researchers found that Rave eCOA helped to motivate patients and increased engagement around experiences outside of the clinical setting, which otherwise may have gone unmentioned. Similarly, many patients reported an increased motivation to report things like activity and sleep, allowing doctors to examine these measures and their implications in cases of serious adverse events. An expanded knowledge of patient quality of life empowered doctors to tailor their disease control approach on an individual patient basis.

The Results

The use of the Medidata cloud-based platform helped the researchers aggregate and process data in real time over the course of the trial, providing valuable insights into patterns of movement and sleep.

Study of these patterns and baseline measurements for other quality of life measurements allowed the researchers to monitor and identify correlations between fluctuations in these measures and adverse events. For chronic malignancies, it is especially crucial to be able to measure and balance the subjective quality-of-life measures with effective treatment. Mobile wearable monitoring may provide objective data to support clinical decision making and utility of treatments. The researchers also identified this format, of electronically-reported patient data, as holding much promise for the future. The use of Rave eCOA here illustrated how real time electronic monitoring can improve the clinical outcomes for patients.

About Medidata

Medidata is leading the digital transformation of life sciences, creating hope for millions of patients. Medidata helps generate the evidence and insights to help pharmaceutical, biotech, medical device and diagnostics companies, and academic researchers accelerate value, minimize risk, and optimize outcomes. More than one million registered users across 1,400 customers and partners access the world's most-used platform for clinical development, commercial, and real-world data.

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