Use of a digital event logger to assess and enhance compliance

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INTRODUCTION

Compliance in clinical studies with topical applications can affect study outcome. Completion of diaries and verbal subject questioning may not produce accurate compliance assessment. Devices are currently available for assessing the opening and closing of pill bottles (1), but no such compliance device exists for the dispensing of topical products.

STUDY METHODS

Eighty-eight female subjects of Fitzpatrick skin type II- IV age 30- 65 years of age were enrolled in an IRB approved, double blinded, 12-week clinical study of a dyspigmentation cosmetic treatment topical. Protocol compliance with the twice daily application of the topical to each of 4 specified face and body locations was recorded via a digital event logger. The topical dispenser (Fig.1) contained a digital event logger to record and store the date, time, and act of dispensing the topical. Data was collected from both the data logging/reporting topical dispenser and an internal data logging function within the device used in application of the topical.

Figure 1. Compliance Monitoring Device

Data from the topical dispenser was transmitted by a wireless cell phone connection to a database where study compliance could be monitored for each subject. Data was shared daily with the study site for the first week to investigate non-compliant subjects and determine the need for immediate follow-up instructions or replacement of non-compliant subjects. Data from the compliance monitoring device was collected and analyzed weekly. Information on the time of day of topical application, frequency and duration of treatment were extracted from analysis of the data from both devices. At the conclusion of the study, data from study subjects who were weakly compliant or non-compliant were considered for removal from the overall data set.

RESULTS

Figure 2 is an example of a non-compliant user whose data was removed from the study data set due to unacceptable compliance as determined by use of the data logging functions.

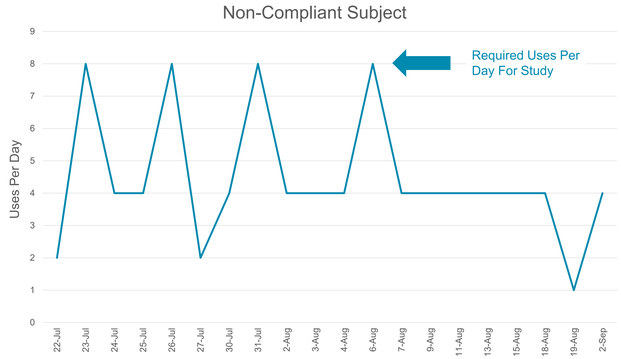


Figure 2. Example of a Non-Compliant Subject. Y axis indicates the number of uses per day over the first 4 weeks, 8 uses being the required frequency per the protocol. X axis is the date of each use of the device.

Figure 3 is an example of correction of subject compliance within the first week of the study followed by continued acceptable compliance.

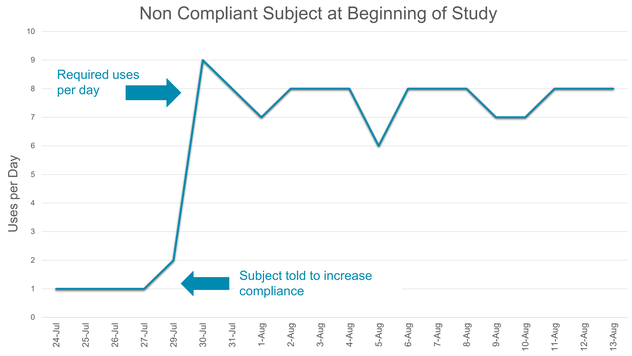
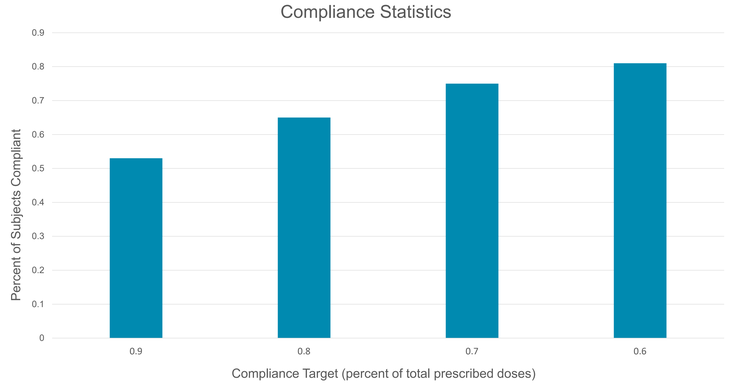


Figure 3. Change in Compliance. Subject was contacted on the 4th day of the study and began closely following the protocol for topical application.

After 1 week, 16% of subjects did not use the topical or used it less frequently than instructed. Two noncompliant subjects discontinued study participation and were replaced. The remaining non-compliant subjects were contacted to correct product compliance.

With continued compliance monitoring during 4 weeks of product use, 93% of subjects correctly applied the topical twice daily as directed. In Figure 4 the percentage of subjects that were compliant is shown using four compliance targets (percentage of total prescribed doses). Fifty-two percent of the subjects exhibited compliance with the study protocol.



RESULTS SUMMARY & DISCUSSION

Remote monitoring of subject compliance through digital event logging can be used to assess subject protocol adherence affording investigators the opportunity to re-educate subjects or replace non- compliant subjects. Using multiple devices to capture data on subjects' actions during a prescribed activity can yield a significant amount of data that can be used to improve the ability of a study to discriminate between arms of the study and interpret results.

REFERENCES

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FINANCIAL DISCLOSURES

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