



## PHT and palmOne Client Success Story

### Merck Research Laboratories Insomnia Study

Research has shown that subjects do not respond as accurately as they could when attempting to recall symptom data after the fact. Handheld eDiaries ensure subjects enter data about their experiences as they happen - anytime, anywhere. As evidenced by the quotes below, however, paper diaries offer no such assurances.

#### Subject Quotes

*On paper diaries...*

"I only had to **play catch up** about **60% of the time.**"

"I sometimes had to **go back a few days** and look at my old answers to see what I should be filling out."

*On the LogPad...*

"It kept me honest - it was like **big brother** watching."

"I was afraid at first but once I tried the practice questionnaires, **it was no problem.**"

#### Objective

The Merck Insomnia Study is the first and only randomized study to compare eDiaries and paper methods of PRO data collection in terms of their relative capability to measure the efficacy of a drug.

#### Study Process

Patients with chronic primary insomnia were randomized to two arms: one using PHT's industry-leading **LogPad® System** (implemented on user-friendly **palmOne™** handheld devices) and one using paper. Subjects ranged in age from 30 to 75 and were treated with an approved and effective insomnia medication.

#### Key Findings

While the demonstrated efficacy was similar for both arms, Merck's results showed that the standard deviation for the study's primary endpoint (change in minutes of total sleep time) was 35% smaller for LogPad data as compared to paper data. Merck calculated that the reduced data variance could enable them to decrease the sample size of future similar trials by 56% while preserving the same study power. Furthermore, Merck found that such a reduction in sample size could result in a savings of up to \$300,000.

#### Additional Benefits

Further advantages of the LogPad System included:

- Time-stamped LogPad data assured analysts that all responses were recorded at the appropriate time. Conversely, it was not possible to verify the actual date and time of paper diary responses
- Stastical properties of the key efficacy parameters suggested that paper data was biased by having been filled in after the fact (*see subject quotes in left margin*)
- Simplified data management resulted from the automatic capture of LogPad data, thereby saving 58 hours of data entry for sites
- Of all five responding sites, 100% were "Quite a Bit" to "Extremely Satisfied" with the LogPad, while none said the same about paper

Results were presented by Merck's Dr. Jay Pearson, Senior Director, Epidemiology Department, and PHT Chief Scientific Officer Dr. Steve Raymond at DIA 2004 and at the International Society for Quality of Life Research (ISOQOL) annual meeting in Boston on June 29, 2004.