

PHT's LogPad®
Direct Clinical Data Collection for Pain Studies

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Introduction

This paper describes the application of the PHT LogPad® to studies in the therapeutic area of pain. It is intended as a summary educational document for readers familiar with clinical trials.

Pain is one of the leading therapeutic areas in which PHT provides firsthand electronic data capture tools. Our work in the areas of neuropathic pain, diverse peripheral neuropathic pain, analgesia, radiculopathy, post-surgical pain and chronic pain, among other indications, is recognized by leading global pharmaceutical companies as pre-eminent in the field of clinical trials.

About PHT Corporation

PHT Corporation is the leading provider of mobile and Web-based electronic data capture products for clinical trials. PHT enables pharmaceutical companies to capture clinical trial data at the point of experience. PHT's product suite enables dramatic improvement in the quality and speed of data collected, thus increasing the scientific value of the trial.

The PHT product suite is built on an open, flexible, and standards-based architecture to ensure that the data collected can be integrated with and into other clinical data management systems and processes. Our customers include some of the leading pharmaceutical, biotechnology, and medical technology companies around the globe. PHT is headquartered in Charlestown, Massachusetts, with its European headquarters in Geneva, Switzerland, and can be found on the Web at www.phtcorp.com.

How the LogPad Works

The LogPad is a handheld electronic device used by clinical sites and subjects to capture patient diary data during a clinical trial. By capturing the data electronically, the LogPad eliminates the need for paper-based diaries. The need to fax or mail paper diaries to a data entry facility is eliminated by the LogPad's ability to securely transmit data to a central server (the Study Server) over analog telephone lines via PHT's LogPad modem – the TeleCradle™. Once transmitted, the data is immediately accessible via PHT web-based StudyWorks software. Sponsors that deploy a LogPad solution have real-time access to data collected from subjects at the point of experience. Data attributability, integrity, and security are insured by the LogPad and StudyWork's compliance with the FDA's 21 CFR Part 11¹.

For the purposes of this paper, all references herein to 'LogPad' will denote a blanket reference to the LogPad and SitePad products offered by PHT Corporation, unless otherwise noted. The name StudyWorks™ refers to PHT's Web-based electronic data capture (EDC) and review product.

¹ See PHT's publication *Compliance with the Food and Drug Administration's 21 CFR Part 11* for further information.

Therapeutic Area: Pain

What's the best way to collect data about subject pain in a clinical trial? The very nature of pain itself and the way it's experienced makes the accurate and complete collection of clinical trial data challenging.

Investigators need to know the true nature of the pain experience in order to collect meaningful data about the efficacy of a pain compound. But the questions require the right answers, answers that are difficult to obtain.

What kind of pain, exactly, is the subject experiencing?
How intense is it?
Where precisely does it hurt?
What is the sensation of pain right now?
How does it feel after taking rescue medication?
How much does the pain interfere with daily activities?

Not surprisingly, subjects often don't immediately record their pain experience when they're using paper diaries. Instead, they may record their pain a few hours or days after they have actually experienced it. For investigators and sponsors, this is problematic. Current pain and other factors significantly influence memory for last pain¹⁻⁵ so retrospective reports of pain intensity may be inaccurate. And recent evidence indicates that paper diaries are typically completed after or even before the time when they are supposed to be done.⁶ Paper diaries aren't able to provide a complete and accurate representation of subject experience and activity.

Conversely, studies have shown that data that's collected at the point of experience is less likely to be fabricated, and may be a truer indication of a subject's pain than data recalled and recorded retrospectively.ⁱ

LogPad® for Pain Studies

PHT's LogPad® is the pharmaceutical and biotechnology industries' pre-eminent device for collecting pain data directly from subjects at the point of experience. Because of LogPad's mobile data capture capabilities, higher quality, more precise pain data is collected. With the LogPad, subjects directly record multiple measures of pain data frequently for extended periods of time.ⁱⁱ Mobile direct data capture with the LogPad results in the collection of denser, richer data that reveals the nuances of the pain experience.

Another important advantage of electronic diaries is that subjects demonstrate remarkably high complianceⁱⁱⁱ when compared with the [compliance] levels of users of paper diaries. Subjects who monitored their pain with an electronic diary entered data 6.75 times a week on average and were 89.9% compliant with daily monitoring during a one-year trial^{iv}. Exit interviews of subjects who participated in a year-long study using electronic diaries provide insight into features that influence compliance with daily diaries. Subjects reported that daily pain monitoring had become part of their routine with electronic diaries. Further, they stated that because of the two-way messaging feature in electronic diaries, they felt that a healthcare provider was closely monitoring their progress and showed concern about the data they were reporting¹¹.

Examples of LogPads for Pain Studies

One crucial key to a successful clinical trial using electronic subject diaries lies within the design and interface of the data capture screens. PHT draws upon its extensive in-house experience in science, technology, and clinical trials to design LogPads that successfully meet the specific data collection needs of each study.

A key LogPad feature is that subjects must fill out all the information on each screen before they can proceed to the next question, resulting in complete data reporting. When using paper measures, subjects can and often do leave some questions unanswered.

The LogPad design takes into account the unique needs of each subject group. For example, in a study with elderly subjects, the typeface on the screens is enlarged for better, easier readability. Our goal is to ensure that your study benefits fully from our LogPad technology.

Validation of the Electronic Visual Analog Scale

An important measurement tool developed by PHT is the electronic Visual Analog Scale. This validated tool has been proven to be as effective at capturing subject pain data as the original paper version, but it offers the enhanced capabilities of immediate, point of experience collection that is usually neglected in paper diaries¹². In addition, there is no time-consuming hand measurement of the VAS, and error-prone transfer of the data to an electronic database. The LogPad calculates the VAS value and places the value in the database directly. Figure 1 provides an example of an eVAS for the LogPad.

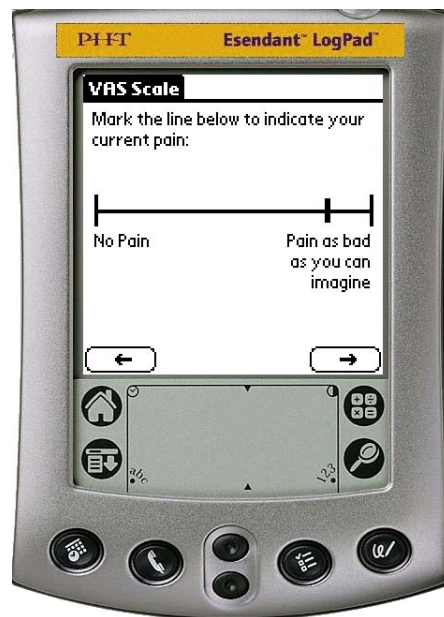


Figure 1 – electronic Visual Analog Scale

The visual analog scale is an established, validated self-reporting measure of pain intensity. The 5-cm electronic VAS on the LogPad has been shown to highly correlate with the results of the traditional 10-cm paper VAS¹³. See the Scatter Graph below.

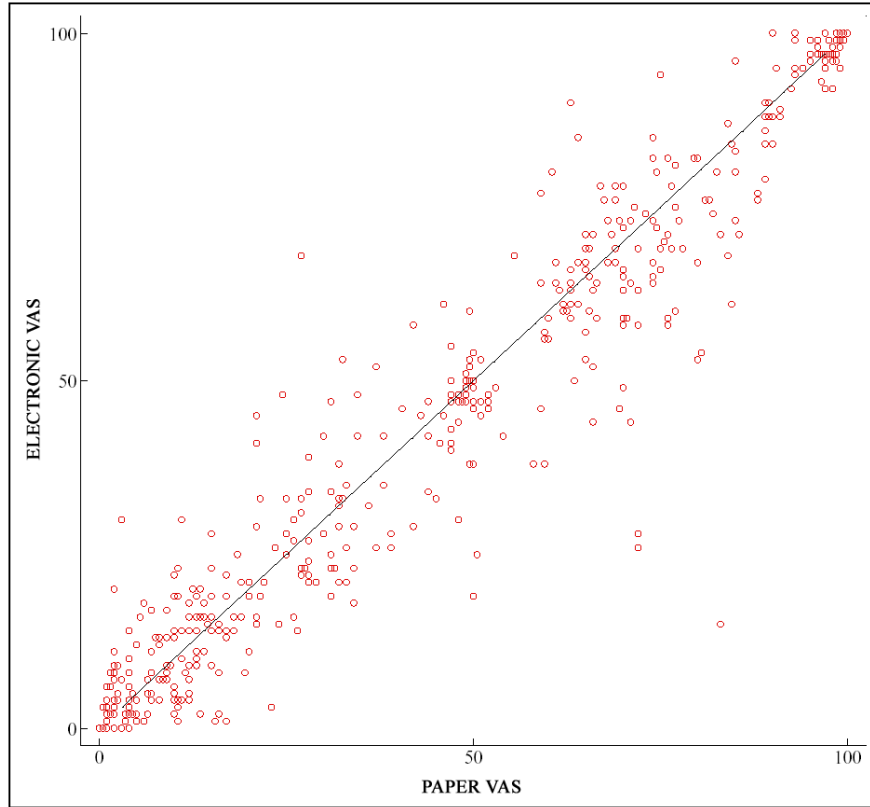


Figure 2: Correlation between eVAS and paper VAS $r = .97$

Body Diagrams

The body diagram screen helps to accurately answer the question, “Where does it hurt?” It enables subject to mark the area(s) of pain they are feeling now precisely and clearly. The body diagram can flip from the ‘front’ position as shown in Figure 2 to the ‘back’ position as shown in Figure 3. Subjects touch the stylus to the “Front/Back” boxes on the right side of the screen to alternate between the two.

The diagram’s visual nature makes it very easy for subjects to mentally image and then record their pain. Subjects can mark more than one area of pain because the diagram is composed of 68 discreet parts. In Figure 3, note that since no part of the body has been selected, the ‘forward’ arrow does not appear on the screen. The subject must touch at least one body part, or choose the ‘no pain’ button in order to proceed to the next screen. This feature, included on every LogPad screen, insures that there will be no missing data.

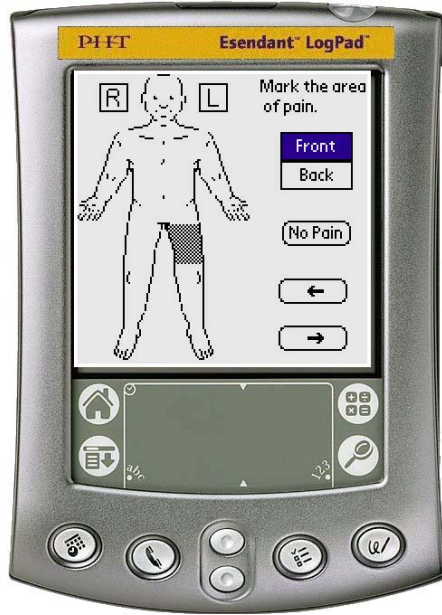


Figure 3: Body Diagram (Front)

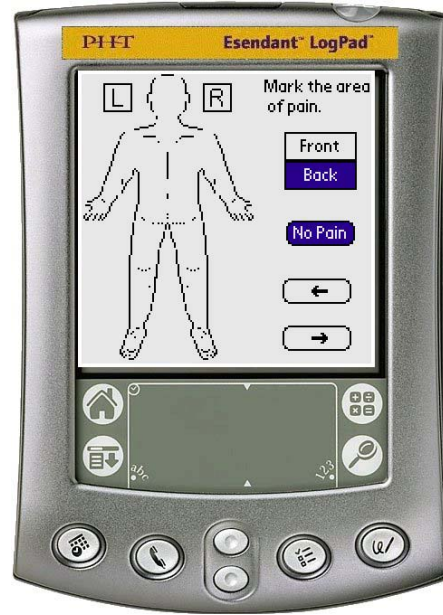


Figure 4: Body Diagram (Back)

Duration Measurement Tools

With a duration measurement tool, subjects easily record the number of minutes of a pain episode. The number spinner makes it easy for the subject to find the correct number immediately, without having to type in digits. This feature is especially important for pain subjects, the elderly, and the visually impaired. This spinner device is one of many used in LogPad screens that take into account the type of subject and his particular needs to successfully complete an electronic diary.

Rescue Medication – Quantity

Subjects record the amount of rescue medication taken with the easy-to-use number spinner. To reduce data entry errors, the screen can be programmed with the dosage range specified in the study protocol.

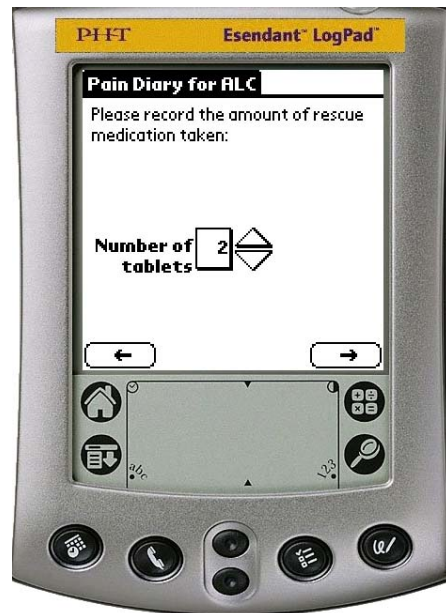


Figure 5: Rescue Medication – Quantity

Rescue Medication – Time Taken

The date spinner makes it easy for subjects experiencing pain to record when they take their rescue medication. The spinner defaults to today's date and exact time. Investigators get accurate information about when rescue meds were taken, often an important viable in accessing compound effectiveness.

Additional Treatments

Multi-select questions are easily accommodated on the LogPad. The design of this particular survey item makes it easy for subjects experiencing pain to report what, if any, additional treatments they have used to alleviate their symptoms. Investigators obtain accurate information about supplementary methods for reducing subject discomfort.

- ¹⁻⁵.1 Peters ML, Sorbi MJ, Kruse DA, Keressens JJ, Verhaak PF, Bensing JM. Electronic diary assessment of pain, disability and psychological adaptation in patients differing in duration of pain. *Pain* 2000 Feb; 84 (2-3): 181-92.
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- ⁱⁱⁱ RN Jamison, JG Levine, SA Raymond, RH Gracely, BL Marino, TJ Hermann, M Daly, D Fram, NP Katz
- ^{iv} Jamison RN, Raymond SA, Levine JG, Slawsby EA, Nedeljkovic SS, Katz NP. Electronic diaries for monitoring chronic pain: 1-year validation study. *Pain* 2001 91: 277 - 285
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- ¹² Jamison RN, Gracely RH, Raymond SA, Levine JG, Marino BL, Herrmann TJ, Daly M, Fram D, Katz NP. Comparative study of electronic vs. paper VAS ratings: a randomized, crossover trial using healthy volunteers. *Pain* 2002; 99 (1-2): 341-347
- ¹³ Ibid.