

LogPad® Use in GI Trials

PHT's Experience with GI Trials

PHT has experience implementing the PHT LogPad® System in a variety of global clinical trials studying Gastrointestinal indications. PHT's experience includes implementations for seven trials studying GI indications with the LogPad collecting both primary and secondary endpoints. For many of these trials, PHT has implemented standard GI questionnaires on the LogPad including: the Irritated Bowel Disease Questionnaire (IBDQ), the Irritable Bowel Syndrome (IBS) Quality of Life (QOL), Crohn's Disease Activity Index (CDAI), the Irritated Bowel Disease Quality of Life (IBDQOL), the IBS Work Productivity and Activity Impairment (WPAI) Questionnaire, and the Patient Assessment of Constipation (PAC) QOL. The LogPad is also capable of displaying graphical images such as those from the Bristol Stool Form scale. PHT has implemented LogPad solutions for a total of ten GI studies to date.

LogPads used in GI Studies

Indication	Trial Phase	# Sites	# Patients	Notes
Irritable Bowel Syndrome	II	35	185	LogPad translated into English and Spanish
Irritable Bowel Syndrome	II	16	200	Deployed in five European countries and translated into five languages
Crohn's Disease	III	35	150	US and Canada, used the Irritable Bowel Disease Questionnaire (IBDQ) on the LogPad, calculation of the Crohn's Disease Activity Index Score (CDAI)
Crohn's Disease	III	35	150	7 European Countries, 8 European Languages
Gastroesophageal Reflux Disease (GERD)	II	100	1000	LogPad used for daily and weekly diaries, sites in the US and Canada
Chronic Constipation	III	170	1026	20 countries, 10 languages, includes stool images, includes the Patient Assessment of Constipation (PAC) QOL.
Irritable Bowel Syndrome	Validation Study	2	72	Using a StudyPad™ for validating the IBS-QOL and IBS-WPAI
Chronic Heartburn	IV	25	330	Post marketing study, US only
Chronic Constipation	IV	18	200	Four countries and three languages,
Constipation	IIIB	120	800	US only

Compliance

On average, the expected LogPad compliance for a trial is 90% and PHT has experience with LogPad compliance ranges from 85-92% in GI studies. PHT has achieved compliance rates as high as 96% in other studies. The key factor in achieving LogPad compliance in a study is to

monitor the subjects using PHT's Data Summaries, which provide real-time information for managing LogPad compliance proactively.

Benefits of Using the LogPad for GI Indications

There are many benefits to using the LogPad in patients with GI diseases. In particular, the information collected from GI patients is confidential and personally sensitive and therefore, a **discrete** mode of data collection is beneficial. In a recent study done with the LogPad in patients suffering from Female Sexual Dysfunction, another sensitive indication, it was found that patients are more likely to record personally sensitive, confidential information into Electronic Patient Diaries than they are onto paper. Please refer to the PHT Press release (http://www.phtcorp.com/News/news_FSD.html) for more information on this finding.

Recording Episodic Information

In GI studies, the LogPad can be used to record both daily diaries and episodic data such as recording details about each bowel movement. The LogPad makes it easy for subjects to record episodes by having the episodic report always available. The LogPad can also provide a "review" report that is always available where subjects can review all of the episodes they entered in the last 18 hours (the time period is configurable) so subjects can be sure they have entered data for every episode they experienced. This has been very helpful in both IBS and Chronic Constipation studies.

Site-based Data Entry: Questionnaires and Assessments

Many LogPads include questionnaires and other data entry enabled or entered by site personnel. Each LogPad contains a "Site Use" button that is password protected and available for sites to access when subjects come in for scheduled visits. Sites can enable questionnaires entered at visits or do assessments of the subjects, i.e the CDAI. The LogPad supports complex calculations, data driven alerts and branching logic any of which can be used by sites and investigators to do scoring or alerting as needed in the protocol.

Time Stamped and Secure Data

All data collected on the LogPad is times stamped and secure. The LogPad includes branching logic and edit checks to ensure the collection of clean and accurate data preventing skipped fields and other errors. The LogPad has a messaging capability that enables direct Site to Patient communication, which has been shown to increase compliance when utilized. The LogPad has alarms that help remind patients to fill out their diaries without interfering with their lifestyle, alarms can be audible, vibrating, or both. The LogPad has a long battery life (up to three weeks without charging), which makes it convenient for patients that travel frequently.

Other benefits of using the LogPad include:

- ◆ **Increased Data Validity**
 - Data is more reliable when recorded electronically from the patient.¹
 - Electronic measurements and scales can be validated (eVAS).²
- ◆ **Reliable Patient Compliance**
 - 11% compliance on paper vs. 90% compliance using electronic patient diary technology
 - 45% of patients forward filled a diary at least once (on paper).³
- ◆ **User Acceptance**
 - Patients prefer using electronic diaries over paper
 - Both patients and sites accept the technology⁴
- ◆ **Proactive trial management**
 - LogPad solution includes web access to enrollment and compliance alerts and metrics and data summaries as well as all of the patient data as it is collected.

- Real-time access to data enables proactive management and monitoring of site enrollment as well as patient compliance.

¹Kamps et. al, 2001. ²Jamison et.al, 2002. ³ Stone et. al, 2002, ⁴ Drummond, et. al, 1995

User Acceptance

A recent study conducted by an outside research company measured Subject and Site response to PHT's LogPad

- ◆ Subjects were aged 60-75, average age of 66
- ◆ Subject comments were enthusiastic:
 - "It's like a game."
 - "Even I can use it."
 - "Can I keep it?"
- ◆ Site reactions were also positive:
 - Sites believed the LogPad improved patient compliance and data quality
 - Delivered successful training to subjects in half an hour
- ◆ Ease of use and convenience were cited by users as LogPad's key benefits

The LogPad is easy to use as the graphical touch screen is intuitive to all types of patient populations. PHT has implemented electronic data capture solutions in over 65 clinical trials at more than 6,500 sites with over 48,000 patients around the globe. LogPads have been used in trials that include geriatric and pediatric patients in 45 languages and 27 countries with no significant difference in compliance based on any patient demographic or disease indication. For more information on the LogPad experience for geriatric populations, visit PHT's website at: <http://www.phtcorp.com/pdf/Geriatric.pdf>.

Examples of LogPad Screens in GI Studies

PHT will customize the LogPad design and branching based on your specific trial questions. Here are some sample screen shots demonstrating the flexible data collection elements that PHT supports.

Episodic Questions

The LogPad can be used to collect information about episodic events such as bowel movements.

Bowel Movement Record

Please enter the date and time of your bowel movement:

Date

Time

←

Bowel Movement Record

Please describe your stool according to the Bristol Stool Form Scale:

- Separate hard lumps, like nuts...
- Sausage-shaped but lumpy
- Like a sausage but with cracks...
- Like a sausage or snake...
- Soft blobs with clear cut edges...
- Fluffy pieces with ragged...
- Watery, no solid pieces


← →

Bowel Movement Record

Please describe your stool according to the Bristol Stool Form Scale:

- Sepa
- Saus
- Like
- Like
- Soft
- Fluff
- Wate

Soft blobs with clear cut edges (easy to pass).



← →

Review Bowel Movements:

On the next screen you can review the bowel movements you have recorded over the past 18 hours:

If you missed recording a bowel movement, please tap the forward arrow and then tap the 'Each BM' button on the main screen.

← →

Review Bowel Movements

	Date:	Time:
1)	16-Mar-2004	04:03
2)	16-Mar-2004	04:03

← →

Daily Diary Questions

The LogPad is frequently used to enter daily diary reports.

Daily Diary, ABC 17 JAN 02

How many bowel movements did you have today?

1

← →

Daily Diary, ABC 17 JAN 02

Have you experienced a feeling of urgency to pass stool today?

Yes

No

← →

Alert

You have indicated that you have had more than 9 bowel movements.

Are you sure that this is correct?

No Yes

Examples of Investigator Assessments

Site personnel including investigators can use the LogPad to capture data. The screens below are examples of the Crohn's Disease Activity Index (CDAI) which was put on a LogPad for a global GI study. The LogPad did the calculation required to score the CDAI which is normally cumbersome to do on paper.

High CDAI Total

The CDAI score recorded is too high per protocol. Please confirm eligibility with the study sponsor

OK

CDAI

Please enter the Date that the IBD symptoms were recorded

Oct / 15 / 2001

← →

CDAI

Is there abdominal mass upon exam ?

No

Questionable

Definitely yes

← →