

PHT LogPad® Experience with CNS Indications (excluding Pain)

PHT’s market leading eDiary product, LogPad, is frequently used in registered clinical trials with indications in the Central Nervous System therapeutic area. LogPad is used in CNS trials to collect clean, timely, and high quality primary and secondary endpoint data from subjects. The LogPad System enables project managers, CRAs and Sites to manage and monitor trial more efficiently with real time reports like LogPad Compliance, Trial enrollment and Daily Diary summary reports.

In CNS trials, LogPad is used to collect daily diary information on outcomes like sleep latency, cigarette cravings, mood, and agitation. LogPad can be used for both scheduled and episodic diaries as required by the specific study protocol and can include a series of scheduled diaries that are triggered on an event like a migraine. LogPads are protocol specific and are customized with a variety of questions and graphical elements like detailed body diagrams and scales including a validated visual analog scale (VAS). LogPads are frequently used to collect data from standardized quality of life questionnaires like the SF36 and standardized disease specific instruments like the Pittsburgh Sleep Index. PHT’s experience with CNS trials includes 16 trials in 19 languages 15 countries around the globe. In addition to the trials listed below, PHT has implemented more than 30 LogPad solutions for clinical trials assessing other pain indications.

PHT LogPad CNS Trial Experience

Indication	Trial Phase	Patients	Sites	Notes
ADHD	IV	280	12	Daily Diary, US and Canada only
ADHD	IV	740	15	Daily Diary, US and Canada only
ADHD	IV	140	2	Daily Diary, US and Canada only
ADHD with Tic Disorder	IV	140	13	Pediatric study, US & Canada, included caregiver module
Bipolarity	IIIb	720	120	19 languages, 15 countries, LCM QOL
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Insomnia	III	160	29	Seven Languages, nine countries, primary endpoints collected on LogPad, SF36, POMS
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Insomnia	Pilot	80	5	Pilot study conducted by Merck Research Labs to assess eDiaries; two arms: paper and LogPad. Results show reduced data variance in LogPad arm by 33%. (Slide set of results available).
Migraine	IIIb	260	15	Pediatric patients ages 12 and older, episodic diary sequence
Migraine	Device Trial	220	20	US, UK, Daily Diary

MS	II	30	4	English, US only, included caregiver module, twice daily diary
Parkinson's Disease	Pilot	12	1	Feasibility to assess use of LogPad in Parkinson's, larger font and targets on LogPad for ease of use, patient feedback was favorable for LogPad
Sleep	III	184	32	Assessing sleep in shift workers
Smoking Cessation	III	360	6	Daily diary
Smoking Cessation	IV	750	1	Daily Included body diagrams for patch site assessment
Metal Health Assessment – SCID Implementation	NIH grant	10	1	PHT was awarded an NIH grant to develop the Structured Clinical Interview (SCID) for DSM-IV assessment tool on a tablet PC.

Questionnaires Used in CNS Trials

The LogPad normally includes a diary completed by the subject on a scheduled basis and questionnaires that are enabled by the Study Coordinator at the site for entry at specific visits. The following questionnaires have been implemented on or are adaptable to the LogPad and are applicable to CNS trials:

- Child Health Questionnaire (CHQ)
- Short Form McGill Pain Questionnaire
- SF-36
- SF-12
- Life Charting Method (LCM)
- Pittsburgh Sleep Quality Index
- Hospital Anxiety and Depression Scale (HADS)
- Profile of Mood States (POMS)
- Beck Depression Inventory
- Cornell Scale for Depression in Dementia
- Geriatric Depression Scale

About PHT

PHT is the global market-leading provider of electronic patient reported outcome (ePRO) solutions for companies that must collect conclusive clinical trial data. PHT's products and services combine mobile and Web technologies with experience-based best practices to improve clinical trial efficiencies through increased data accuracy, higher data yield per patient, and real-time access to trial data. PHT has implemented more ePRO solutions than any other provider; our experience includes more than 110 clinical trials with over 50,000 patients.