Health Decisions

*Women's health*

# A Framework for Successful Pain Measurement in Clinical Studies

Due to its complex nature, designing a study that effectively measures pain intensity and/or relief can be challenging. Health Decisions offers these considerations based on previous experience managing pain trials:

### Defining Study Objectives

Pain is multidimensional, which can make it tedious to define study endpoints. Endpoints may measure pain intensity and frequency, interference with emotional/physical functioning and general quality of life.

### Choosing a Measurement Tool

An objective physiologic marker of pain does not currently exist, meaning study coordinators must rely on patient reported data gathered through questionnaires and other tools to assess outcomes. The type and aspects of pain being measured drive tool selection; for instance, acute pain can be measured using a unidimensional visual, numerical or ordinal tool, whereas chronic pain requires a multi-dimensional tool.

### Establishing a Reporting Schedule

Clearly defined timeframes for capturing pain scores must be addressed with site staff to ensure consistency in reporting. If post-surgical, the protocol must account for the impact of surgical medications and consider how pain will be scored if a patient is asleep to ensure subject experience is accurately captured.

### Clarifying Event Reporting

Study staff should have clear guidelines on how to classify and report adverse events and serious adverse events. The protocol should define thresholds for expected pain, worsening of pain and triggers for recording adverse events.

### Addressing Addiction

Due to the addictive nature of some pain medications, regulatory requirements typically mandate additional assessments for abuse potential. Study staff must be appropriately trained to administer these assessments.

### Accounting for Subject Differences

Pain is subjective. A subject's personal beliefs, age, culture and mood can impact how they describe their pain experience. Data has shown gender differences in pain response, with women reporting greater sensitivity than men. Subject education is critical to alleviate biases and ensure accurate reporting of pain.

### Defining Rescue Interventions

Use of rescue medications must be consistent across all sites. The study protocol should provide a threshold for when and how rescue medications are to be used, permitted and excluded.

### Site Selection

Sites must have the proper licenses to store and administer medications, including protocol-defined rescue therapies. Standard materials should be provided outlining study processes and best practices, including patient engagement/training methods. If possible, hold an in-person investigator meeting where calibration and pain certification trainings can be conducted.

### Trial Design and Statistical Analysis

The complexities of capturing pain can make the analysis of study outcomes difficult. A trial must be strategically designed and appropriately analyzed so study endpoints can be evaluated effectively.

Health Decisions recognizes the value that improved pain treatment can provide women and society. We regularly contribute deep expertise to clinical studies spanning development strategy, design, site oversight, data monitoring, statistical analysis, reporting and publication. Connect with a Health Decisions expert to discuss plans for clinical research in pain measurement.

If you are developing women's health products -

## Make Your First Decision the Right Decision - Health Decisions

**The Leading Full-Service Women's Health CRO from Pre-IND or -IDE to Regulatory Approval and Beyond**

Health Decisions is a full-service CRO specializing in the clinical development of drugs, diagnostics, medical devices and combination drug/devices in all areas of women's health as well as development of diagnostics for all therapeutic areas. Our experience, expertise, site network and KOL and investigator relationships enable us to address the challenges of developing women's health products in areas including general gynecology, contraception, sexual health, infertility, obstetrics, menopause and osteoporosis and other indications that affect women disproportionately and profoundly, including autoimmune disorders and male-factor infertility. Health Decisions is headquartered in Durham, NC.

Health Decisions
2510 Meridian Pkwy
Durham, NC 27713

Tel: +1.919.967.1111
Toll Free: +1.888.779.3771
Email: contact@healthdec.com

For more information
please visit
www.HealthDec.com

Health Decisions