Centralized Peak Flow

b i o m e d i c a l s y s t e m s

Clinical Trials and Centralized Peak Flow

Lung diseases such as asthma, COPD, and cystic fibrosis decrease a patient's air flow by narrowing or blocking the airways during exhalation. Peak flow is a simple, non-invasive and inexpensive method to measure the function of the airway. Biomedical Systems recommends using an electronic peak flow meter with integrated text based diary for clinical trials for home peak flow data capture. Recent studies have shown a 89% patient compliance rate for patients using this type of system as compared to a 44% compliance rate for patients using manual diaries.†

† "Analysis of Peak Flow Monitoring When Recording of Data is Electronic"

Flexible Solutions To Accommodate Your Trial

Biomedical Systems experienced team of Project Managers and Respiratory Therapists will work with you every step of the way to make your study smooth and seamless. In addition to excellent, professional customer service, your study will receive:

- Peak flow software with ediary capability customized to your protocol specifications which, provides unique features for capturing and centralizing home Peak Flow data.
- Capture and centralization of data may include:
  - 3 data collection periods per day
  - Up to 10 diary questions available
  - Pin number protected units to prevent unauthorized use
  - Patient alarms and exacerbation reports based upon medication usage
  - Patient alarms and exacerbation reports based on answers to diary questions
  - Central over-read for data quality and patient compliance
  - Full review of flow volume loops by site personnel
- Tracking for acute episodes as well as safety monitoring
- Standardized equipment, operating procedures and comprehensive quality control procedures generate accurate, reliable data
- Site equipment includes laptop computer, modem and electronic peak flow devices
- Protocol-specific training manual clarifies process
- Manual and electronic quality control checks
- Web-based Sponsor access to data and reports

Global Capabilities

- Participating in trials in over 75 countries, 11,000 clinical sites
- Offices in North America, Europe & Asia
- Multilingual staff fluent in 20 languages to facilitate communication with sites
- Phase I through Phase IV studies
- Single Project Manager assigned per study

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Biomedical Systems Peak Flow Workflow

Standardized equipment and software sent to all sites in study

Peak Flow data sent via Easy PFT Web Server to Biomedical Systems

Received data is stored in protocol specific database as well as disk backup

Manual and computerized Sponsor defined edits checks performed within 24 hours

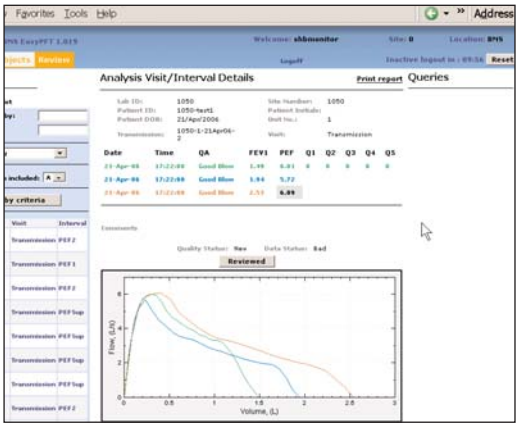
Data query issued to site within 24 hours. Queries are re-issued daily until resolved

Credentialed Respiratory professionals review all Peak Flow tests for Quality and Acceptability based on ATS, ERS and Sponsor defined requirements

Data converted into Sponsor defined format, SAS, ASCII, etc.

Clean database submitted to Sponsor

Biomedical Systems offers Sponsors web access to Peak Flow data via our Easy PFT web portal.



For more information or to schedule a presentation, please contact a Biomedical Systems' Representative at 800-877-6334 in North America or 32-2-661-20-70 in Europe. Or access our website at www.biomedsys.com.

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