

Centralized Spirometry

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

Clinical Trials and Centralized Spirometry

Spirometry is one of the most common pulmonary function tests available to help identify and diagnose lung disease. As pharmaceutical and biopharmaceutical companies continue to develop new compounds for the treatment of diseases such as Asthma, Chronic Obstructive Lung Disease (COPD), and Cystic Fibrosis, simple Spirometry is frequently used as a cost-effective, non-invasive method of documenting efficacy. However, pulmonary function testing is an effort-dependent test that requires patient cooperation and understanding of the proper testing technique to obtain quality data. In 1994, Biomedical Systems pioneered the first centralized spirometry study used in a multi-site clinical trial. We continue to be the innovators in pulmonary data collection, analysis, quality review, site management and training for international clinical trials.

Biomedical Systems' Proven Centralized Approach

When you trust a study to Biomedical Systems, you can be sure that our 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 and professional customer service, your study will receive:

- Customized software designed to meet protocol requirements, ensures data security and automatically transmits data. Software is programmed with screen alerts prompting sites to perform tests exactly as designed ensuring that uniform and quality data.

- Protocol-specific training manuals that clarify procedures for site personnel
- Standardized spirometry computer systems and equipment options are available
- SOPs and comprehensive quality control for accurate, reliable data
- RRT review of flow loops per ATS/ERS guidelines
- Manual and electronic quality control checks
- 21 CFR and HIPPA Compliant
- Web-based Sponsor access to data and reports



Standardized equipment and software ensure consistent data quality

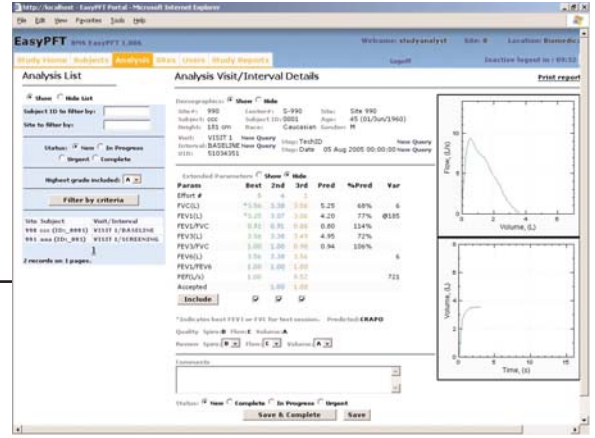
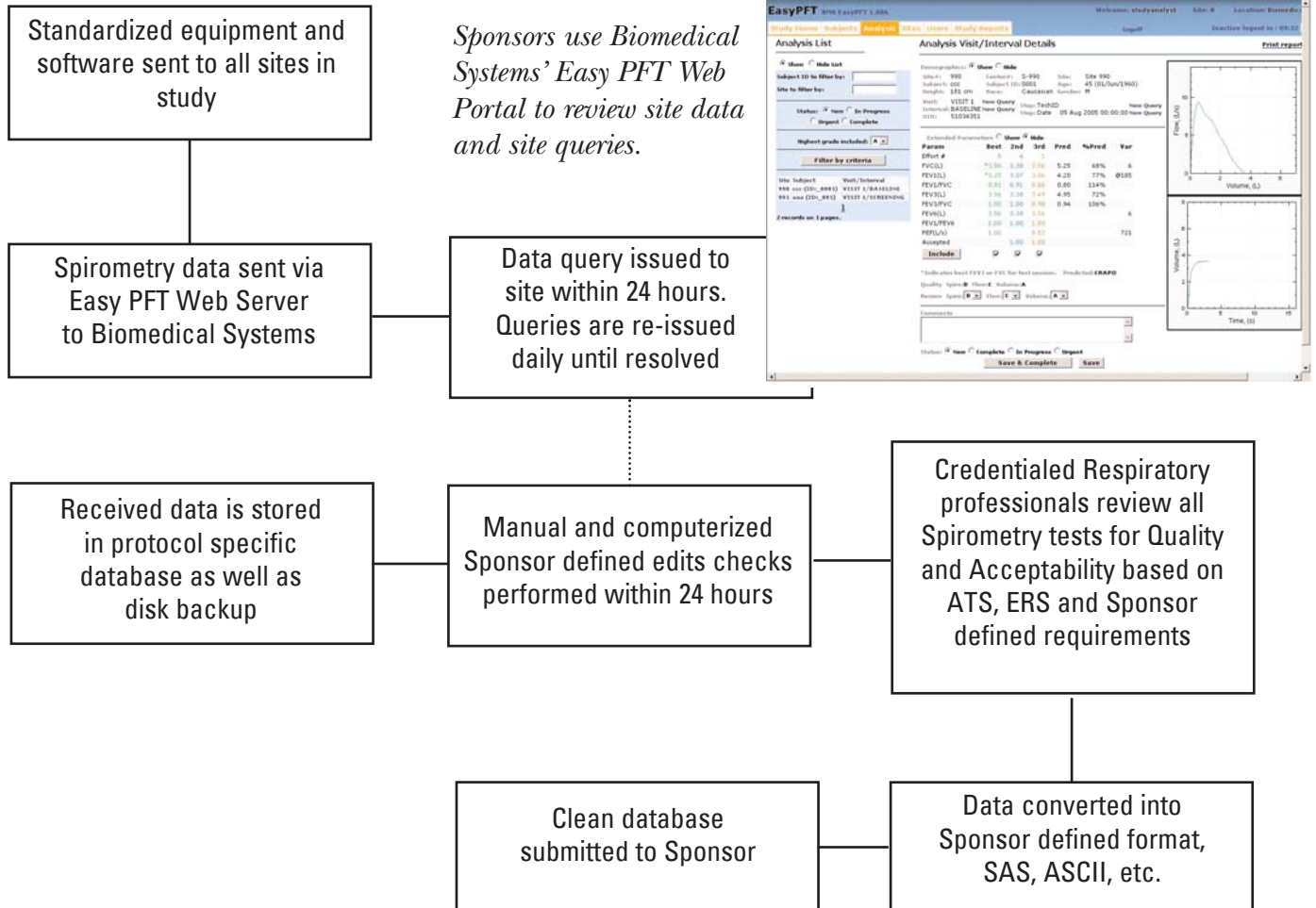
Global Capabilities

- 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



Spirometry

Biomedical Systems Spirometry Workflow



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.



www.biomedsys.com

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