



The
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Uniform Data System for Medical Rehabilitation

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Functional Assessment And Outcomes Research

“As we function, so shall we live”

Carl V. Granger, MD
Founder and Executive Director
UDSMR

UDSMR Clinical Trial Licensing and Collection Services Functional and quality-of-life tools

Uniform Data System for Medical Rehabilitation (UDSMR) is an affiliate of the not-for-profit University at Buffalo Foundation Activities, Inc., that for over 20 years has been the industry leader in providing reliable functional outcomes reporting and benchmarking services to the rehabilitation field both domestically and internationally. UDSMR created an outcomes measurement tool known as the FIM[®] instrument. The FIM[®] instrument is widely accepted by rehabilitation professionals worldwide as the gold standard for measuring function. This instrument is used to assess a patient's physical and cognitive status before and after therapeutic services for many conditions, including stroke, spinal cord injury, traumatic brain injury, joint replacement and Multiple Sclerosis. UDSMR also developed a pediatric adaptation of the FIM[®] instrument known as the WeeFIM[®] instrument. Due to an increase of interest in pediatric research, the WeeFIM[®] instrument has been licensed for use in several pediatric clinical trials. Responding to the need for measurement tools relative to the outpatient setting, UDSMR's LIFEwareSM System tracks outcomes for a diverse range of patient populations, including those with: musculoskeletal, neurological, memory, pain and joint specific conditions. The LIFEwareSM System is comprised of measurements for evaluating patients across seven core functional domains: physical and cognitive function, mood or affect, pain, social interaction, role participation and satisfaction with treatment.

With the clinical trial industry's increasing need for patient reported (PRO) and clinically assessed outcomes, UDSMR's experience, expertise, integrity, innovation and quality of support continues to serve a vital role in trial outcomes for some of the world's largest cutting edge biotech, pharmaceutical and medical device companies. Regardless of the medical disease or condition your trial may be striving to alleviate or overcome, restoring physical and/or cognitive function to the patient is essential to your trial's success.

UDSMR can assist in the following ways:

- **Phase II, III, and IV studies:** The measurement of physical and cognitive function can be crucial to demonstrating the efficacy, effectiveness and safety of a technology, therapy, or intervention and provide quantifiable outcomes that can lend credence to these clinical markers. Our functional assessment tools measure such variables as effect on health status, quality of life, functional improvement and reduced treatment costs.
- **Assistance with protocol development:** Our experts help to develop a protocol for the data collected with our licensed instruments.
- **Health Related Quality of Life studies:** Collection of the SF-36v2, its derivatives and the EQ-5D to help assess health disparities and measure the cost effectiveness of interventions. Development and establishment of the psychometric properties of HRQoL measurement tools.
- **Customized CRF design:** We help to develop study specific forms.
- **Secure, remote data collection on a global basis*:** Our trained professionals offer remote telephonic data collection on a global scale in the areas of functional assessment and quality-of-life instruments. Our systems contain state of the art security and technology and we have over 20 years experience in handling sensitive patient information in a confidential manner. *HIPAA compliant in the United States
- **FIM[®] instrument, WeeFIM[®] instrument and LIFEwareSM System licensing:** We offer educational and training materials to assist you in performing your own assessments, as well as testing materials to ensure uniformity in the administration of the instrument leading to greater reliability in comparative data.
- **Statistical analysis:** We provide analytical services for “triple blind” trials and any trial looking for impartial analysis of their data to avoid possible conflict of interest issues with study outcomes. Analytical services offered include, but are not limited to: bivariate and multivariate data analysis (such as, ANOVA, MANOVA, correlations, Chi Square, linear and logistic regression modeling, multilevel modeling, C&RT analysis), odds ratios and relative risk, sensitivity and specificity of new and established measures, transforming skewed data, samples matching, power analysis, analysis for repeated measures designs and risk adjustment (direct and indirect as well as development of new methodologies for comparisons).

Current and past clients have included:

Janssen Biotech, Inc. (f/k/a Centecor Ortho Biotech Inc.) - 800 Ridgeview Rd., Horsham, PA 19044
Medtronic International Trading Sàrl - Route du Molliau 31, CH-1131 Tolochenaz, Switzerland
StemCells, Inc. - 3155 Porter Drive, Palo Alto, CA 94304