

Challenging Patient Populations

Pediatric

- 50% of NERI clinical trials and registries include pediatric subjects encompassing 22,290 subjects across 490 U.S. and international research sites, many with required subject retention over several years.
- NERI scientific thought leaders understand the challenges associated with pediatric research, including study design, informed consent and assent, regulatory submissions, and subject recruitment.
- NERI is the Data Coordinating Center for the NIH Pediatric Heart Network and numerous clinical registries, notably in pediatric cardiomyopathy and thalassemia.

Elderly

- NERI studies in older patient populations have included menopause, osteoporosis, sexual health, and urinary incontinence in aging women and BPH, prostatitis, hypogonadism, urology, erectile dysfunction, and bone density in aging men, as well as clinical trials in heart failure, cardiogenic shock, and other cardiovascular diseases.
- NERI's ground-breaking epidemiological work with the Massachusetts Male Aging Study (MMAS) and the Advanced Cognitive Training for Independent and Vital Elderly study (ACTIVE) are leading examples of NERI's contributions to previously unexplored areas of research.

Orphan

- From Marfan Syndrome and sickle cell anemia to pulmonary hypertension, NERI has a wealth of experience in conducting clinical trials and registries in orphan indications.
- NERI has a proven track record of working closely with sites, patient advocacy groups, and non-profit organizations to meet specific study goals and timelines.

“I am very proud of NERI's accomplishments in conducting clinical trials, registries, and epidemiological research in challenging patient populations. NERI's commitment to research that addresses the unmet medical needs of elderly and pediatric patients, often in orphan indications, is unparalleled in the industry.”

John McKinlay, PhD

Senior Vice President and Director

CASE STUDY: Pediatric Neuromuscular Disease

Details:

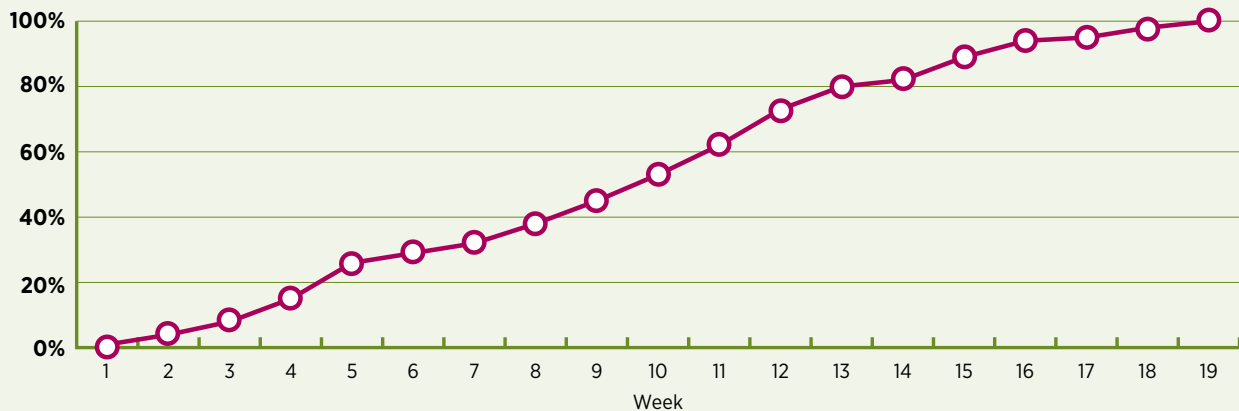
- Phase III non-interventional study
- Orphan indication
- 120 pediatric subjects (diseased and healthy cohorts)
- 18 clinical study sites
- 2 countries (U.S., Canada)

CASE STUDY: Pediatric Neuromuscular Disease (continued)

Key Highlights:

- Conducted extensive site training in how to present study opportunity to parents
- Created and trained sites in an outreach strategy for enrolling healthy volunteers via friends, siblings, and families of enrolled subjects
- Created and trained sites in community and physician outreach strategies to enroll healthy volunteers
- Conducted study coordinator training in the accurate use of a motor function scale to ensure inter-rater reliability
- Enrolled 100% of subjects in 19 weeks

Percent Subjects Enrolled



Global Services

- Phase II - IV, Registries
- Study Feasibility
- Protocol Design
- Project Management
- Regulatory Affairs
- Site Selection, Recruitment, and Management
- Clinical Monitoring and Training
- Data Management
- Biostatistics
- Quality Assurance

Specialized Capabilities

- Drug, Biologics, Biomaterials, and Medical Device Studies
- Pediatric, Elderly, and Orphan Indication Studies
- Biomarker Studies
- Complex Instrument Design, Development, and Pre-Testing
- Biologic Specimen Collection and Tracking
- Biologic Specimen Repository Set-Up and Management
- Complex Data Extraction and Cleaning
- Proprietary CTMS/EDC
- Proprietary IVRS/IWRS

To learn more about NERI's Challenging Patient Populations Experience, please contact our Business Development Department:

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