

## Patient Registry Services

Patient registries have evolved from basic lists of people with specific medical conditions into complex databases that carefully monitor disease states and track outcomes of medical interventions. Today's patient registries, whether disease-based, observational, or product-focused, are vital resources for capturing real-world patient information.

NERI patient registries achieve multiple scientific, commercial, and regulatory goals to provide:

- Much needed information on the natural history of rare conditions
- Source of potential patients for clinical trial participation that results in rapid recruitment
- Patient-reported outcomes, generalized findings, and tracking data
- Post-market surveillance to meet regulatory requirements of the Food and Drug Administration (FDA)
- Data to meet reimbursement requirements of the Centers for Medicare and Medicaid Services (CMS)

NERI understands industry's rapidly expanding need for patient registries. NERI provides sponsors with in-depth expertise in the creation, coordination, analysis, and management of large, and often disparate, datasets. NERI is highly experienced in combining data from active registries and clinical trials into a single registry with ongoing patient follow-up for long-term safety and effectiveness.

NERI has a wealth of experience successfully conducting national and international multicenter registries, as well as natural history studies with complex longitudinal data and patient-reported outcomes. NERI's extensive expertise in multi-site, international clinical trials, epidemiology, survey research, health care services, and outcomes research further enhances our unparalleled capabilities in registry design and implementation.

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"NERI is the recognized leader in creating, analyzing, and merging complex datasets that comprise robust patient registries. Through these unmatched services, industry sponsors rely on NERI's invaluable contributions to evidence-based medicine."

**Raymond C. Rosen, PhD**  
Chief Scientist

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### CASE STUDY: Pediatric Cardiomyopathy Patient Registry

- 3,500 subjects over 12+ years
- 90 clinical study sites
- 2 countries (U.S., Canada)
- Objectives to collect incidence data, management practices, and clinical outcomes
- 4 studies conducted to date:
  - Longitudinal Functional Status assessment
  - Prospective Cohort study
  - Drug Safety Surveillance study
  - Pediatric Heart Transplant study

#### Key Highlights:

- Collect clinical data, demographics, imaging measurements, Quality of Life measures, and biologic specimens (blood and myocardial tissue)
- Set-up and manage long-term Biologic Specimen Repository
- Merge third-party registry data post-transplant to create comprehensive datasets within HIPAA constraints

### Selected Patient Registry Experience

Indication	# Patients	# Sites	Site Locations
Abdominal Aortic Aneurysms	581	18	United States
Cardiogenic Shock	1,189	36	North America, Europe, Latin America, Australasia
Cardiovascular	500	5	United States
Cardiovascular (Pediatric/Orphan)	3,500	90	North America
Carotid Revascularization	19,000	93	United States
Catastrophic Thoracic Aortic Indications	200	5	United States
Female Hypoactive Sexual Desire Disorder	1,500	35	United States
Hepatitis C	1,050	12	United States
Male Hypogonadism	1,000	20	Europe
Post Traumatic Stress Disorder	1,600	1	United States
Sickle Cell Anemia (Pediatric/Orphan)	209	38	North America
Thalassemia (Pediatric/Orphan)	864	20	North America, Europe
Thoracic Aortic Aneurysms	40	1	United States
Vascular	354	13	United States

To learn more about NERI's Patient Registry Services, please contact our Business Development Department:

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