



DS³ Overview

PSI INTERNATIONAL, Inc. (PSI), a Fairfax, Virginia-based company, was initially established in 1977 to provide Information Technology (IT) services. Since that time, we have effectively expanded our capabilities and subject matter expertise to include the areas of Health Science, Social Services, and other technical disciplines. Over the years we have developed and maintained an impressive resource pool of professionals which has earned the respect of our global client community.

PSI's Health Science practice provides a broad base of services to our government and global commercial clients. PSI supports various phases of the new drug development life cycle:

- ◆ PSI's experienced scientists and clinicians facilitate clinical research by offering expert advice in the planning, coordination, and monitoring of all facets of clinical trial initiatives
- ◆ Through our support of the Food and Drug Administration (FDA) and the National Cancer Institute's Cancer Therapy Evaluation Program, PSI has gained an in-depth understanding of the best means to achieve and maintain operational compliance with the published policies and guidance of the FDA, including 21 CFR Part 11
- ◆ We are thoroughly adept at navigating the regulatory process, including developing and processing Investigational New Drug Applications, Adverse Event Reports, Annual Reports, Investigator's Brochures, and various legal agreements.

What is DS³

PSI's premier Drug Safety Support Services, *DS³*, is within our Health Science practice and is the result of many years of experience in providing Drug Safety services and solutions globally. It includes:

- ◆ Data Entry and Data Entry Quality Control (QC)
- ◆ Safety Review, including Coding, Coding QC, and Narrative Writing
- ◆ Aggregate Reporting
- ◆ Medical Review
- ◆ Scientific Writing
- ◆ Training
- ◆ Risk Management Services
- ◆ Information Technology.

PSI's *DS³* is available at the client site or at PSI provided facilities. We offer full outsourcing of drug safety functions, such as adverse event processing services as well as assistance in supporting specific activities, such as coding files on a "one time basis" or routine support over an extended period of time.

PSI has applied lessons learned over the years regarding the collection, classification, storage, retrieval, analysis and interpretation of data related to the safety and effectiveness of drugs. PSI's staff of subject matter experts has developed each component of *DS³* as a value added function focused on specific challenges faced by our clients in the Drug Safety sector of biopharmaceutical business.

PSI provides DS³ through a highly experienced pool of Subject Matter Experts that include:

- ◆ Program Managers
- ◆ Health Care Professionals
 - Physicians
 - Pharmacists
 - Nurses
- ◆ Statisticians
- ◆ Analysts
- ◆ Data Entry Managers
- ◆ Imaging Specialists
- ◆ Information Technologists
- ◆ Medical Terminology Specialists
- ◆ Drug Safety Associates.

PSI's Subject Matter Experts represent practical experience at the regulatory and industry level on multiple continents. PSI's combines our subject matter expertise with our technology experience and promotes the development of innovative tools, methodologies, and technologies in a nurturing environment to solve real life Drug Safety problems. By using our solutions, the clients improve their resource management, decrease their productivity problems and can focus on their core mission of developing effective and safe drugs.

A representative subset of unique solutions developed by PSI includes:

- ◆ Computer Based Training Courses
- ◆ Electronic Certification and Training (eCert)
- ◆ Life Cycle Development of Adverse Event Reporting Systems
- ◆ Unique MedDRA queries for Data Retrieval.

Of course, these solutions are complemented by such services as:

- ◆ MedDRA Support Services
 - Consulting
 - Coding
 - Training
 - Quality Control
- ◆ WHO-DD Support Services
 - Consulting
 - Coding and
 - Training.

For more information about our MedDRA services, visit our web site at www.MedDRAHelp.com or contact:

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