



WHO-DD Support Services 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 a 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.

PSI's premier Drug Safety Support Services, *DS³*, is within our Health Science practice and 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 corporate 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.

Maximize Your Use of WHO Drug Dictionaries

Despite and, perhaps, due to the comprehensive and robust nature of the WHO's Drug Dictionaries (DD, DDE, Herbal) - collectively referred hereafter as **WHO-DD**, the biopharmaceutical industry continues to struggle to fully realize their true potential. The most commonly reverberated statement in the industry seems to be, "we are not fully realizing our Return on Investment (ROI) on the work related to medical terminologies and dictionaries." Many have come to realize that they don't have knowledgeable and properly trained personnel to code consistently in WHO-

DD. Of course the issues of high personnel turnover, on-going expansion of WHO-DD, training and retraining of personnel, and comprehending the full scope of the dictionaries and their true value only further complicate the decision maker's job of earmarking and justifying corporate investment in supporting their WHO-DD needs.

Organizations continue to look for and invest in external resources to support their WHO-DD requirements. Unfortunately, they realize that there is a real shortage of experienced, hands-on WHO-DD experts who can provide proven, reliable and comprehensive support to organizations around the world. They soon discover that the solutions offered by these organizations, with limited practical experience in WHO-DD, are eventually costing their organizations more dollars and time because the solutions implemented lack standards, consistency and accuracy. Many of them have approached PSI to 'fix' these inappropriately implemented solutions and provide 'true experts' to assist them in protecting their future WHO-DD investments.

Perhaps it is time for you too to increase your ROI by working with an expert organization that can transfer comprehensive WHO-DD knowledge, built over numerous years of practical hands-on experience, to your personnel. PSI will establish a partnership with your internal team, provide consultation support, and train them to take full advantage of WHO-DD, keeping in mind the issues of consistency, coding guidelines and accuracy of coding. A partnership with PSI will reduce your direct cost while having a positive impact

on the indirect cost of your internal resources.

PSI and World Health Organization's (WHO) Uppsala Monitoring Center (UMC) which is the developer and maintainer of WHO-DD, have established an alliance to support WHO-DD by increasing the knowledge base of its users through education and training. The services available through this alliance capitalize on the success of both companies in their respective areas of expertise. UMC is the absolute authority on WHO-DD and PSI is a proven expert which specializes in assisting companies and organizations in realizing the true value of medical terminologies within their environment. PSI has joined UMC as the North American Training Partner to provide a suite of UMC Certified Training Courses. The benefit of this alliance to the client is a knowledge transfer model supported by PSI's experts and backed by the owners of the Drug Dictionary - UMC. This allows the clients to concentrate on their core mission while reaping full benefits of the WHO-DD offering.

PSI Offers a Total WHO-DD Solution

As UMC's partner, PSI offers the most comprehensive and proven WHO-DD solutions to clients worldwide. Our WHO-DD experts are health care professionals who possess a wealth of first-hand, practical experience gained from implementing WHO-DD and other dictionary/terminology solutions over 50 clients on four continents.

PSI is a world leader in providing a complete suite of WHO-DD solutions to clients. Our unparalleled experience has taught us that each of our clients has

unique needs and requires customized and personal support from our team of WHO-DD experts. Three basic principles guide us in solving our customers' WHO-DD problems:

1. We focus on clients' goals by working closely with each one as their partner and a member of their team;
2. We use the most appropriate tools and are not predisposed to certain solutions or products; and
3. We transfer knowledge to realize solutions.

Our WHO-DD support services include Implementation Consulting, Coding, and Training.

Implementation Consulting Support

PSI provides a full range of WHO-DD consulting support services by providing consultants who:

- ◆ Are PSI-certified to engage in consulting services
- ◆ Have undergone specialized WHO-DD training
- ◆ Possess a minimum of three years experience in coding and Quality Control (QC).

PSI experts have on-going consultations with their counterparts at UMC and hence, have comprehensive understanding of WHO-DD and other products. Their relationship also allows us to leverage the collective knowledge in providing the best level of service to our clients. PSI Consultants are fully qualified to offer high quality of services to our customers in:

- ◆ *Strategic planning support* for WHO-DD implementation throughout their organization worldwide
- ◆ *Developing and maintaining coding guidelines* to achieve consistency in coding
- ◆ *On-site consulting and augmenting the client's staff* in providing services such as corporate orientation, support of internal client meetings, quality control of the coding done by others, and Help Desk support.

Coding Support

PSI has an experienced pool of WHO-DD coding experts who are successful health care professionals. These experts have worked with us for years and have mastered the PSI coding methodology. Our methodology employs a three-tiered quality assurance process where we review all coded terms to ensure coders are adhering to WHO-DD coding best practices and the customer coding standards and guidelines.

The coding services that we provide to our clients include:

- ◆ *Coding outsourcing* to clients who believe it is beneficial to have a third party perform remote coding
- ◆ *On-site coding support* where we have experienced coders on-site to assist the customer's coding team
- ◆ *Quality assurance activities and monitoring* to ensure consistency among the customer's internal coding team or their support coding entities such as Contract Research Organizations (CROs).

Training Support

PSI offers an extensive line of UMC Certified WHO-DD Training Services. We have the most comprehensive and

practical classroom training available today, customizable to the needs of each customer. PSI offers courses at convenient locations in North America and at customer sites worldwide. PSI also offers UMC-developed Computer-based training in WHO-DD. All of our courses are based on lessons learned while implementing WHO-DD for the industry. All of our instructors have supported industry clients in multiple countries and have qualified as PSI coding, quality assurance and implementation experts.

We offer the following standard courses:

- ◆ *WHO-DD :Fundamentals-Computer Based Training*
- ◆ *WHO-DD :Training for Coders*
- ◆ *WHO-DD :Data Retrieval and Analysis*
- ◆ *WHO-DD : IT Support Concepts*
- ◆ *Coding With the Masters: Interactive Workshop (May be tailored for MedDRA and/or WHO-DD)*

PSI: Uniquely Qualified

PSI is uniquely qualified to meet your WHO-DD needs because, we offer:

- ◆ *Unmatched Experience* – You will benefit from our vast practical experience and Lessons Learned over the years and yet pay only for the effort we spend on your project

- ◆ *Customized Approach* – We develop individualized WHO-DD solutions that fit your organization. We produce efficient reports by rolling up our sleeves and working closely with you to the extent you request.
- ◆ *IT Support Concepts **Unparalleled Resources*** – We have a pool of WHO-DD experts who have been carefully chosen and trained for many years. They have practical WHO-DD insights rarely available elsewhere. Thus, no matter how large your need, we can accommodate you.
- ◆ *Flexible Cost Model* – Our business model is cost effective and suitable for small as well as large companies. Our pricing is competitive; PSI is not a product company and has no costs for software or a superfluous product to recover.

For more information about PSI's WHO-DD services, please visit our web site at www.psiint.com or contact:

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